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Sec. 1395nn. Limitation on certain physician referrals

- (a) Prohibition of certain referrals
  - (1) In general
    Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then -
    - (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
      (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).
  - (2) Financial relationship specified
    For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is -
    - (A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or
    - (B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.
      An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

- (b) General exceptions to both ownership and compensation arrangement prohibitions
  Subsection (a)(1) of this section shall not apply in the following cases:
  - (1) Physicians' services
    In the case of physicians' services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4) of this section) as the referring physician.
  - (2) In-office ancillary services
    In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies) -
    - (A) that are furnished -

- (i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and
  (ii)(I) in a building in which the referring physician (or another physician who is a member of the same group practice)
  furnishes physicians' services unrelated to the furnishing of designated health services, or
- (II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice -

- (aa) for the provision of some or all of the group's clinical laboratory services, or

- (bb) for the centralized provision of the group's designated health services (other than clinical laboratory services),
  unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, and
  (B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice,
  if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
  - (3) Prepaid plans
    In the case of services furnished by an organization -
    - (A) with a contract under section 1395mm of this title to an individual enrolled with the organization,
    - (B) described in section 1395l(a)(1)(A) of this title to an individual enrolled with the organization,
    - (C) receiving payments on a prepaid basis, under a demonstration project under section 1395b-1(a) of this title or under section 222(a) of the Social Security Amendments of 1972, to an individual enrolled with the organization, or
    - (D) that is a qualified health maintenance organization (within the meaning of section 300e-9(d) [1] of this title) to an individual enrolled with the organization.
  - (4) Other permissible exceptions
    In the case of any other financial relationship which the

Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

- (c) General exception related only to ownership or investment prohibition for ownership in publicly traded securities and mutual funds
  Ownership of the following shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:
  - (1) Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are -
  - (A)
    - (i) securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or
    - (ii) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and (B) in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding $75,000,000.

- (2) Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if such company had, at the end of the company's most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75,000,000.

- (d) Additional exceptions related only to ownership or investment prohibition
  The following, if not otherwise excepted under subsection (b) of this section, shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:
  - (1) Hospitals in Puerto Rico
    In the case of designated health services provided by a hospital located in Puerto Rico.
  - (2) Rural provider
    In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by an entity, if substantially all of the designated health services furnished by such entity are furnished to individuals residing in such a rural area.

- (3) Hospital ownership
  In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if -
  - (A) the referring physician is authorized to perform services at the hospital, and
    (B) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

- (e) Exceptions relating to other compensation arrangements
  The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B) of this section:
  - (1) Rental of office space; rental of equipment
    - (A) Office space
      Payments made by a lessee to a lessor for the use of premises if -
      - (i) the lease is set out in writing, signed by the parties, and specifies the premises covered by the lease,
      - (ii) the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's

        rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas,
      - (iii) the lease provides for a term of rental or lease for at least 1 year,
      - (iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume
        or value of any referrals or other business generated between the parties,
      - (v) the lease would be commercially reasonable even if no referrals were made between the parties, and
        (vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
    - (B) Equipment
      Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if -
      - (i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,

- (ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,
- (iii) the lease provides for a term of rental or lease of at least 1 year,
- (iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume
or value of any referrals or other business generated between the parties,
- (v) the lease would be commercially reasonable even if no referrals were made between the parties, and
(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

- (2) Bona fide employment relationships
Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if -
  - (A) the employment is for identifiable services,
  - (B) the amount of the remuneration under the employment -
    - (i) is consistent with the fair market value of the services, and
    (ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,
  - (C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and
  (D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
  Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).
- (3) Personal service arrangements
  - (A) In general
  Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) if -
    - (i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,

- (ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,
- (iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,
- (iv) the term of the arrangement is for at least 1 year,
- (v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
- (vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and
  (vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

- (B) Physician incentive plan exception
  - (i) In general
    In the case of a physician incentive plan (as defined in clause (ii)) between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:
- (I) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.
- (II) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary pursuant to section 1395mm(i)(8)(A)(ii) of this title, the plan complies with any requirements the Secretary may impose pursuant to such section.
- (III) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of this clause.
  - (ii) "Physician incentive plan" defined
    For purposes of this subparagraph, the term "physician

incentive plan" means any compensation arrangement between
an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

- (4) Remuneration unrelated to the provision of designated health services
  In the case of remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services.
- (5) Physician recruitment
  In the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital, if -
  - (A) the physician is not required to refer patients to the hospital,
  - (B) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and
    (C) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
- (6) Isolated transactions
  In the case of an isolated financial transaction, such as a one-time sale of property or practice, if -
  - (A) the requirements described in subparagraphs (B) and (C) of paragraph (2) are met with respect to the entity in the same manner as they apply to an employer, and
    (B) the transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
- (7) Certain group practice arrangements with a hospital
  - (A) [2] In general
    [2] So in original. No subpar. (B) has been enacted.
    An arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if -
    - (i) with respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1395x(b)(3) of this title.
    - (ii) the arrangement began before December 19, 1989, and has continued in effect without interruption since such date,

- (iii) with respect to the designated health services covered under the arrangement, substantially all of such services furnished to patients of the hospital are furnished by the group under the arrangement,
- (iv) the arrangement is pursuant to an agreement that is set out in writing and that specifies the services to be provided by the parties and the compensation for services provided under the agreement,
- (v) the compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
- (vi) the compensation is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the entity, and
  (vii) the arrangement between the parties meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

- (8) Payments by a physician for items and services
  Payments made by a physician -
  - (A) to a laboratory in exchange for the provision of clinical laboratory services, or
  - (B) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.

- (f) Reporting requirements
  Each entity providing covered items or services for which payment may be made under this subchapter shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including -
  - (1) the covered items and services provided by the entity, and
    (2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A) of this section), or with a compensation arrangement (as described in subsection (a)(2)(B) of this section), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity. Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides [3] services for which payment may be made under this subchapter very infrequently.

- (g) Sanctions
  - (1) Denial of payment
    No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of this section.
  - (2) Requiring refunds for certain claims
    If a person collects any amounts that were billed in violation of subsection (a)(1) of this section, the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.
  - (3) Civil money penalty and exclusion for improper claims
    Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than $15,000 for each such service. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.
  - (4) Civil money penalty and exclusion for circumvention schemes
    Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.
  - (5) Failure to report information
    Any person who is required, but fails, to meet a reporting requirement of subsection (f) of this section is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

- (6) Advisory opinions
  - (A) In general
    The Secretary shall issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section. Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.
  - (B) Application of certain rules
    The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4) of this section and take into account the regulations promulgated under subsection (b)(5) of section 1320a-7d of this title in the issuance of advisory opinions under this paragraph.
  - (C) Regulations
    In order to implement this paragraph in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.
  - (D) Applicability
    This paragraph shall apply to requests for advisory opinions made after the date which is 90 days after August 5, 1997, and before the close of the period described in section 1320a-7d(b)(6) of this title.

- (h) Definitions and special rules
  For purposes of this section:
  - (1) Compensation arrangement; remuneration
    - (A) The term "compensation arrangement" means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).
    - (B) The term "remuneration" includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.
    - (C) Remuneration described in this subparagraph is any remuneration consisting of any of the following:

- (i) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

- (ii) The provision of items, devices, or supplies that are used solely to -

- (I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or
- (II) order or communicate the results of tests or procedures for such entity.

- (iii) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if -
  - (I) the health services are not furnished, and the payment is not made, pursuant to a contract or other arrangement between the insurer or the plan and the physician,
  - (II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to such individual,
  - (III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and
    (IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
    - (2) Employee
      An individual is considered to be "employed by" or an "employee" of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).
    - (3) Fair market value
      The term "fair market value" means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.
    - (4) Group practice
  - (A) Definition of group practice
    The term "group practice" means a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association -

- (i) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel,

- (ii) for which substantially all of the services of the physicians who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group,

- (iii) in which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined,

- (iv) except as provided in subparagraph (B)(i), in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician,

- (v) in which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice, and
  (vi) which meets such other standards as the Secretary may impose by regulation.
    - (B) Special rules

- (i) Profits and productivity bonuses
  A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.

- (ii) Faculty practice plans
  In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) shall be applied only with respect to the services provided within the faculty practice plan.
    - (5) Referral; referring physician

- (A) Physicians' services
  Except as provided in subparagraph (C), in the case of an item or service for which payment may be made under part B of this subchapter, the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician), constitutes a "referral" by a "referring physician".
- (B) Other items
  Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a "referral" by a "referring physician".
- (C) Clarification respecting certain services integral to a consultation by certain specialists
  A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician".

- (6) Designated health services
  The term "designated health services" means any of the following items or services:
  - (A) Clinical laboratory services.
  - (B) Physical therapy services.
  - (C) Occupational therapy services.
  - (D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
  - (E) Radiation therapy services and supplies.
  - (F) Durable medical equipment and supplies.
  - (G) Parenteral and enteral nutrients, equipment, and supplies.
  - (H) Prosthetics, orthotics, and prosthetic devices and supplies.
  - (I) Home health services.
  - (J) Outpatient prescription drugs.
  - (K) Inpatient and outpatient hospital services.

Footnotes

[1] See References in Text note below.

[3] So in original. Probably should be "provide".

(c) *Conditional primary payments: Exceptions.* HCFA does not make conditional Medicare primary payments if—

(1) The LGHP denies the claim in whole or in part for one of the following reasons:

(i) It is alleged that the LGHP is secondary to Medicare.

(ii) The LGHP limits its payments when the individual is entitled to Medicare.

(iii) The LGHP does not provide the benefits to individuals who are entitled to Medicare on the basis of disability and covered under the plan by virtue of current employment status but does provide the benefits to other similarly situated individuals enrolled in the plan.

(iv) The LGHP takes into account entitlement to Medicare in any other way.

(v) There was failure to file a proper claim for any reason other than physical or mental incapacity of the beneficiary.

(2) The LGHP, an employer or employee organization, or the beneficiary fails to furnish information that is requested by HCFA and that is necessary to determine whether the LGHP is primary to Medicare.

(d) *Limit on secondary payments.* The provisions of § 411.172(e) also apply to services furnished to the disabled under this subpart.

Subpart I—[Reserved]

Subpart J—Physician Ownership of, and Referral of Patients or Laboratory Specimens to, Entities Furnishing Clinical Laboratory or Other Health Services

SOURCE: 60 FR 41978, Aug. 14, 1995, unless otherwise noted.

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for clinical laboratory services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered items or services under Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by HCFA.

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Compensation arrangement means any arrangement involving any remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity.

Direct supervision means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

Employee means any individual who, under the usual common law rules that

apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed at 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

Fair market value means the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, *fair market value* means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

Financial relationship refers to a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

(1) An ownership or investment interest that exists in the entity through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing laboratory services; or

(2) A compensation arrangement with the entity.

Group practice means a group of two or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions:

(1) Each physician who is a *member of the group*, as defined in this section, furnishes substantially the full range of patient care services that the physician routinely furnishes including medical care, consultation, diagnosis, and treatment through the joint use of shared office space, facilities, equipment, and personnel.

(2) Except as provided in paragraphs (2)(i) and (2)(ii) of this definition, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) are furnished through the group and billed in the name of the group and the amounts received are treated as receipts of the group. "Patient care services" are measured by the total patient care time each member spends on these services. For example, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing countable patient care services.

(i) The "substantially all" test does not apply to any group practice that is located solely in an HPSA, as defined in this section, and

(ii) For group practices located outside of an HPSA (as defined in this section) any time spent by group practice members providing services in an HPSA should not be used to calculate whether the group practice located outside the HPSA has met the "substantially all" test, regardless of whether the members' time in the HPSA is spent in a group practice, clinic, or office setting.

(3) The practice expenses and income are distributed in accordance with methods previously determined.

In the case of faculty practice plans associated with a hospital, institution of higher education, or medical school that has an approved medical residency training program in which faculty practice plan physicians perform specialty and professional services, both within and outside the faculty practice, as well as perform other tasks such as research, this definition applies only to those services that are furnished within the faculty practice plan.

Hospital means any separate legally organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills. A "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital.

HPSA means, for purposes of this regulation, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in 42 CFR part 5, appendix A, part I—Geographic Areas). In addition, with respect to dental, mental health, vision care, podiatric, and pharmacy services, an HPSA means an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for dental professionals, mental health professionals, vision care professionals, podiatric professionals, and pharmacy professionals, respectively.

Immediate family member or member of a physician's immediate family means husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Members of the group means physician partners and full-time and part-time physician contractors and employees during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

Patient care services means any tasks performed by a group practice member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters. They can include, for example, the services of physicians who do not directly treat patients, time spent by a physician consulting with other physicians, or time spent reviewing laboratory tests.

Physician incentive plan means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of items or services.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, any item or service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if—

(i) The request is part of a consultation initiated by another physician; and

(ii) The tests or services are furnished by or under the supervision of the pathologist.

Referring physician means a physician (or group practice) who makes a referral as defined in this section.

Remuneration means any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Transaction means an instance or process of two or more persons doing business. An *isolated transaction* is one involving a single payment between two or more persons. A transaction that involves long-term or installment payments is not considered an isolated transaction.

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a financial relationship with an entity, or who has an immediate family member who has a financial relationship with the entity, may not make a referral to that entity for the furnishing of clinical laboratory services for which payment otherwise may be made under Medicare.

(b) *Limitations on billing.* An entity that furnishes clinical laboratory services under a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the clinical laboratory services performed under that referral.

(c) *Denial of payment.* No Medicare payment may be made for a clinical laboratory service that is furnished under a prohibited referral.

(d) *Refunds.* An entity that collects payment for a laboratory service that was performed under a prohibited referral must refund all collected amounts on a timely basis.

§ 411.355 General exceptions to referral prohibitions related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physicians' services,* as defined in § 410.20(a), that are furnished personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

(b) *In-office ancillary services.* Services that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.

(ii) A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member.

(iii) An entity that is wholly owned by the physician or the physician's group practice.

(c) *Services furnished to prepaid health plan enrollees by one of the following organizations:*

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M, of this chapter.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U, of this chapter.

(3) An organization that is receiving payments on a prepaid basis for the enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with HCFA under section 1857 of the Act and part 422 of this chapter.

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

[60 FR 41978, Aug. 14, 1995, as amended at 63 FR 35066, June 26, 1998]

§411.356 Exceptions to referral prohibitions related to ownership or investment interests.

For purposes of §411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be purchased on terms generally available to the public and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

(2) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding $100 million; or

(ii) Stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in §412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

§ 411.357 Exceptions to referral prohibitions related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing and is signed by the parties and specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease are set in advance and are consistent with fair market value.

(5) The charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing and signed by the parties and specifies the equipment covered by the lease.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee.

(3) The lease provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(5) The lease would be commercially reasonable even if no referrals were made between the parties.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements.* (1) *General.* Remuneration from an entity

under an arrangement to a physician or immediate family member of the physician, including remuneration for specific physicians' services furnished to a nonprofit blood center, if the following conditions are met:

(i) The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term of the arrangement is for at least 1 year.

(v) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled in the entity.

(ii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii) of the Act, the plan complies with any requirements the Secretary has imposed under that section.

(iii) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of paragraph (d)(2) of this section.

(3) Until January 1, 1995, the provisions in paragraph (d)(1) and (2) of this section do not apply to any arrangements that meet the requirements of section 1877(e)(2) or section 1877(e)(3) of the Act as they read before they were amended by the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

(e) *Physician recruitment.* Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(1) The arrangement and its terms are in writing and signed by both parties.

(2) The arrangement is not conditioned on the physician's referral of patients to the hospital.

(3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital.

(4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the conditions set forth in paragraphs (c)(2) and (c)(3) of this section are met with respect to an entity in the same manner as they apply to an employer. There can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions which are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* (1) Until January 1, 1995, any compensation arrangement between a hospital

and a physician or a member of a physician's immediate family if the arrangement does not relate to the furnishing of clinical laboratory services; or

(2) Remuneration provided by a hospital to a physician if the remuneration does not relate to the furnishing of clinical laboratory services.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which clinical laboratory services are provided by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before December 19, 1989, and has continued in effect without interruption since then.

(3) With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with an agreement that is set out in writing and that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group.

(b) A newly-formed group practice (one in which physicians have recently begun to practice together) or any group practice that has been unable in the past to meet the requirements of section 1877(h)(4) of the Act must—

(1) Submit a written statement to attest that, during the next 12-month period (calendar year, fiscal year, or next 12 months), it expects to meet the 75-percent standard and will take measures to ensure the standard is met; and

(2) At the end of the 12-month period, submit a written statement to attest that it met the 75-percent standard during that period, billed for those services under a billing number assigned to the group, and treated amounts received for those services as receipts of the group. If the group did not meet the standard, any Medicare payments made for clinical laboratory services furnished by the group during the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier no later

than 60 days after receipt of the attestation instructions from its carrier.

[60 FR 41978, Aug. 14, 1995, as amended at 60 FR 63440, Dec. 11, 1995]

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as HCFA specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.

(c) *Required information.* The information submitted to HCFA under paragraph (a) of this section must include at least the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician who has an immediate relative (as defined in § 411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if requested by HCFA).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary. Entities are given at least 30 days from the date of the carrier's or intermediary's request to provide the initial information. Thereafter, an entity must provide updated information within 60 days from the date of any change in the submitted information. Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to HCFA or the OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 for each day of the period beginning on the day following the applicable deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to HCFA under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

§ 411.370 Advisory opinions relating to physician referrals.

(a) *Period during which HCFA will accept requests.* The provisions of §§ 411.370 through 411.389 apply to requests for advisory opinions that are submitted to HCFA after November 3, 1997, and before August 21, 2000, and to any requests submitted during any other time period during which HCFA is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from HCFA concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, HCFA determines whether a business arrangement described by the parties to that arrangement appears to constitute a "financial relationship" (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral

prohibition described in section 1877 of the Act.

(1) The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. HCFA does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* HCFA does not address through the advisory opinion process—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* HCFA considers requests for advisory opinions that involve applying specific facts to the subject matter described in paragraph (b) of this section. Requestors must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in § 411.372.

(e) *Requests that will not be accepted.* HCFA does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity;

(2) HCFA is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) HCFA believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, HCFA, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

[63 FR 1655, Jan. 9, 1998]

§ 411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to HCFA in writing, including an original request and 2 copies. The request must be addressed to: Health Care Financing Administration, Department of Health and Human Services, Attention: Advisory Opinions, P.O. Box 26505, Baltimore, MD 21207.

(b) *Information HCFA requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with HCFA on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including: the purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved) and any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal services

or employment contracts, leases, deeds, pension or insurance plans, financial statements, or stock certificates (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

(iii) Detailed statements of all collateral or oral understandings, if any; and

(iv) Descriptions of any other arrangements or relationships that could affect HCFA's analysis.

(5) Complete information on the identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and § 411.351), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions the requestor would like HCFA to address including, if possible, a description of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions to the prohibition the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a-7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in § 411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(9) A check or money order payable to HCFA in the amount described in § 411.375(a).

(c) *Additional information HCFA might require.* If the request does not contain all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, HCFA believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in § 411.373.

[63 FR 1655, Jan. 9, 1998]

§ 411.373 Certification.

(a) Every request must include the following signed certification: "With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief."

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: "The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter." This statement may be made contingent on a favorable advisory opinion, in which case the requestor should add

one of the following phrases to the certification:

(1) "if HCFA issues a favorable advisory opinion."

(2) "if HCFA and the OIG issue favorable advisory opinions."

[63 FR 1656, Jan. 9, 1998]

§ 411.375 Fees for the cost of advisory opinions.

(a) *Initial payment.* Parties must include with each request for an advisory opinion submitted through December 31, 1998, a check or money order payable to HCFA for $250. For requests submitted after this date, parties must include a check or money order in this amount, unless HCFA has revised the amount of the initial fee in a program issuance, in which case, the requestor must include the revised amount. This initial payment is nonrefundable.

(b) *How costs are calculated.* Before issuing the advisory opinion, HCFA calculates the costs the Department has incurred in responding to the request. The calculation includes the costs of salaries, benefits, and overhead for analysts, attorneys, and others who have worked on the request, as well as administrative and supervisory support for these individuals.

(c) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If HCFA estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, HCFA notifies the requestor.

(3) If HCFA notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, HCFA stops processing the request until the requestor makes a written request for HCFA to continue. If HCFA is delayed in processing the request for an advisory opinion because of this procedure, the time within which HCFA must issue an advisory opinion is suspended until the requestor asks HCFA to continue working on the request.

(4) If the requestor chooses not to pay for HCFA to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs HCFA has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs HCFA has incurred in responding to the request are greater than the amount the requestor has paid, HCFA, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. HCFA does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid HCFA the total amount due for the costs of processing the request, HCFA issues the advisory opinion. The time period HCFA has for issuing advisory opinions is suspended from the time HCFA notifies the requestor of the amount owed until the time HCFA receives full payment.

(d) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that HCFA notifies the requestor that it needs an outside expert opinion until the time HCFA receives that opinion.

[63 FR 1656, Jan. 9, 1998]

§ 411.377 Expert opinions from outside sources.

(a) HCFA may request expert advice from qualified sources if HCFA believes that the advice is necessary to respond to a request for an advisory opinion. For example, HCFA may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If HCFA determines that it needs to obtain expert advice in order to issue a requested advisory opinion, HCFA notifies the requestor of that

fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in § 411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once HCFA has received payment for the estimated cost of the expert advice, HCFA arranges for the expert to provide a prompt review of the issue or issues in question. HCFA considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs HCFA has incurred in responding to the request, and the responsibility of the requestor, as described in § 411.375(c).

[63 FR 1657, Jan. 9, 1998]

§ 411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before HCFA issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in § 411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in § 411.375. HCFA reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

[63 FR 1657, Jan. 9, 1998]

§ 411.379 When HCFA accepts a request.

(a) Upon receiving a request for an advisory opinion, HCFA promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, HCFA—

(1) Formally accepts the request for an advisory opinion;

(2) Notifies the requestor about the additional information it needs, or

(3) Declines to formally accept the request.

(c) If the requestor provides the additional information HCFA has requested, or otherwise resubmits the request, HCFA processes the resubmission in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) Upon accepting the request, HCFA notifies the requestor by regular U.S. mail of the date that HCFA formally accepted the request.

(e) The 90-day period that HCFA has to issue an advisory opinion set forth in § 411.380(c) does not begin until HCFA has formally accepted the request for an advisory opinion.

[63 FR 1657, Jan. 9, 1998]

§ 411.380 When HCFA issues a formal advisory opinion.

(a) HCFA considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized HCFA official.

(b) An advisory opinion contains a description of the material facts known to HCFA that relate to the arrangement that is the subject of the advisory opinion, and states HCFA's opinion about the subject matter of the request based on those facts. If necessary, HCFA includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1905.

(c)(1) HCFA issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that HCFA determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first business day following the weekend or holiday;

(3) The 90-day period is suspended from the time HCFA—

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in § 411.375(c)(2) until HCFA receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until HCFA receives the additional information;

(iii) Notifies the requestor of the full amount due until HCFA receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until HCFA receives the expert advice.

(d) After HCFA has notified the requestor of the full amount owed and has received full payment of that amount, HCFA issues the advisory opinion and promptly mails it to the requestor by regular first class U.S. mail.

[63 FR 1657, Jan. 9, 1998]

§ 411.382 HCFA's right to rescind advisory opinions.

Any advice HCFA gives in an opinion does not prejudice its right to reconsider the questions involved in the opinion and, if it determines that it is in the public interest, to rescind or revoke the opinion. HCFA provides notice to the requestor of its decision to rescind or revoke the opinion so that the requestor and the parties involved in the requestor's arrangement may discontinue any course of action they have taken in accordance with the advisory opinion. HCFA does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon HCFA's advice under this part, provided—

(a) The requestor presented to HCFA a full, complete and accurate description of all the relevant facts; and

(b) The parties promptly discontinue the action upon receiving notice that HCFA had rescinded or revoked its approval, or discontinue the action within a reasonable "wind down" period, as determined by HCFA.

[63 FR 1657, Jan. 9, 1998]

§ 411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that HCFA issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after HCFA issues an advisory opinion and releases it to the requestor, HCFA makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the DHHS/HCFA web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by HCFA, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to HCFA in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits HCFA's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action HCFA has taken in response to the request.

[63 FR 1657, Jan. 9, 1998]

§ 411.386 HCFA's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. HCFA has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

[63 FR 1658, Jan. 9, 1998]

§ 411.387 Parties affected by advisory opinions.

An advisory opinion issued by HCFA does not apply in any way to any individual or entity that does not join in the request for the opinion. Individuals or entities other than the requestor(s) may not rely on an advisory opinion.

[63 FR 1658, Jan. 9, 1998]

§ 411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that

the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

[63 FR 1658, Jan. 9, 1998]

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only HCFA's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, HCFA's advisory opinion cannot be read to indicate HCFA's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that HCFA issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[63 FR 1658, Jan. 9, 1998]

Subpart K—Payment for Certain Excluded Services

§ 411.400 Payment for custodial care and services not reasonable and necessary.

(a) *Conditions for payment.* Notwithstanding the exclusions set forth in § 411.15 (g) and (k). Medicare pays for "custodial care" and "services not reasonable and necessary" if the following conditions are met:

(1) The services were funished by a provider or by a practitioner or supplier that had accepted assignment of benefits for those services.

(2) Neither the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know, that the services were excluded from coverage under § 411.15 (g) or (k).

(b) *Time limits on payment.* (1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, payment may not be made for inpatient hospital care, posthospital SNF care, or home health services furnished after the earlier of the following:

(i) The day on which the beneficiary has been determined, under § 411.404, to have knowledge, actual or imputed, that the services were excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(ii) The day on which the provider has been determined, under § 411.406 to have knowledge, actual or imputed, that the services are excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(2) *Exception.* Payment may be made for services furnished during the first day after the limit established in paragraph (b)(1) of this section, if the PRO or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. It the PRO or the intermediary determines that yet another day is necessary for planning post-discharge care, payment may be made for services furnished during the second day after the limit established in paragraph (b)(1) of this section.

§ 411.402 Indemnification of beneficiary.

(a) *Conditions for indemnification.* If Medicare payment is precluded because the conditions of § 411.400(a)(2) are not met. Medicare indemnifies the beneficiary (and recovers from the provider, practitioner, or supplier), if the following conditions are met:

(1) The beneficiary paid the provider, practitioner, or supplier some or all of the charges for the excluded services.

(2) The beneficiary did not know and could not reasonably have been expected to know that the services were not covered.

(3) The provider, practitioner, or supplier knew, or could reasonably have been expected to know that the services were not covered.

(4) The beneficiary files a proper request for indemnification before the end of the sixth month after whichever of the following is later:

(i) The month is which the beneficiary paid the provider, practitioner, or supplier.

(ii) The month in which the intermediary or carrier notified the beneficiary (or someone on his or her behalf) that the beneficiary would not be liable for the services.

For good cause shown by the beneficiary, the 6-month period may be extended.

(b) *Amount of indemnification.*[1] The amount of indemnification is the total that the beneficiary paid the provider, practitioner, or supplier.

(c) *Effect of indemnification.* The amount of indemnification is considered an overpayment to the provider, practitioner, or supplier, and as such is recoverable under this part or in accordance with other applicable provisions of law.

§ 411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A beneficiary who receives services that constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k), is considered to have known that the services were not covered if the criteria of paragraphs (b) and (c) of this section are met.

(b) *Written notice.* Written notice has been given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines. A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion. For example, program payment may not be made for the treatment of obesity, no matter what form the treatment may take. After the beneficiary who is treated for obesity with dietary control is informed in writing that Medicare will not pay for treatment of obesity, he or she will be presumed to know that there will be no Medicare payment for any form of subsequent treatment of this condition, including use of a combination of exercise, machine treatment, diet, and medication.

(c) *Source of notice.* The notice was given by one of the following:

(1) The PRO, intermediary, or carrier.

(2) The group or committee responsible for utilization review for the provider that furnished the services.

(3) The provider, practitioner, or supplier that furnished the service.

§ 411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services which constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

(b) *Notice from the PRO, intermediary or carrier.* The PRO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending phyician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from the provider, practitioner, or supplier to the beneficiary.* Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that—

(1) The services were not covered; or

(2) The beneficiary no longer needed covered services.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of HCFA notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a PRO.

[1] For services furnished before 1988, the indemnification amount was reduced by any deductible or coinsurance amounts that would have been applied if the services had been covered.

(2) FEDERAL REGISTER publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 48425, Sept. 19, 1995]

§ 411.408 Refunds of amounts collected for physician services not reasonable and necessary, payment not accepted on an assignment-related basis.

(a) *Basic rule.* Except as provided in paragraph (d) of this section, a physician who furnishes a beneficiary services for which the physician does not undertake to claim payment on an assignment-related basis must refund any amounts collected from the beneficiary for services otherwise covered if Medicare payment is denied because the services are found to be not reasonable and necessary under § 411.15(k).

(b) *Time limits for making refunds.* A timely refund of any incorrectly collected amounts of money must be made to the beneficiary to whom the services were furnished. A refund is timely if—

(1) A physician who does not request a review within 30 days after receipt of the denial notice makes the refund within that time period; or

(2) A physician who files a request for review within 30 days after receipt of the denial notice makes the refund within 15 days after receiving notice of an initial adverse review determination, whether or not the physician further appeals the initial adverse review determination.

(c) *Notices and appeals.* If payment is denied for nonassignment-related claims because the services are found to be not reasonable and necessary, a notice of denial will be sent to both the physician and the beneficiary. The physician who does not accept assignment will have the same rights as a physician who submits claims on an assignment-related basis, as detailed in subpart H of part 405 and subpart B of part 473, to appeal the determination, and will be subject to the same time limitations.

(d) *When a refund is not required.* A refund of any amounts collected for services not reasonable and necessary is not required if—

(1) The physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service; or

(2) Before the service was provided—

(i) The physician informed the beneficiary, or someone acting on the beneficiary's behalf, in writing that the physician believed Medicare was likely to deny payment for the specific service; and

(ii) The beneficiary (or someone eligible to sign for the beneficiary under § 424.36(b) of this chapter) signed a statement agreeing to pay for that service.

(e) *Criteria for determining that a physician knew that services were excluded as not reasonable and necessary.* A physician will be determined to have known that furnished services were excluded from coverage as not reasonable and necessary if one or more of the conditions in § 411.406 of this subpart are met.

(f) *Acceptable evidence of prior notice to a beneficiary that Medicare was likely to deny payment for a particular service.* To qualify for waiver of the refund requirement under paragraph (d)(2), of this section, the physician must inform the beneficiary (or person acting on his or her behalf) that the physician believes Medicare is likely to deny payment.

(1) The notice must—

(i) Be in writing, using approved notice language;

(ii) Cite the particular service or services for which payment is likely to be denied; and

(iii) Cite the physician's reasons for believing Medicare payment will be denied.

(2) The notice is not acceptable evidence if—

(i) The physician routinely gives this notice to all beneficiaries for whom he or she furnishes services; or

(ii) The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the service.

(g) *Applicability of sanctions to physicians who fail to make refunds under this*

section. A physician who knowingly and willfully fails to make refunds as required by this section may be subject to sanctions as provided for in chapter V, parts 1001, 1002, and 1003 of this title.

[55 FR 24568, June 18, 1990; 55 FR 35142, 35143, Aug. 28, 1990]

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

Subpart A—General Provisions

Subpart B—Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

Subpart D—Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

Subpart E—Determination of Transition Period Payment Rates for the Prospective Payment System for Inpatient Operating Costs

Subpart F—Payment for Outlier Cases

Subpart G—Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs

Subpart H—Payments to Hospitals Under the Prospective Payment Systems

Subparts I–J—[Reserved]

Subpart K—Prospective Payment System for Inpatient Operating Costs for Hospitals Located in Puerto Rico

Subpart L—The Medicare Geographic Classification Review Board

Subpart M—Prospective Payment System for Inpatient Hospital Capital Costs

5. *Manufacturing controls.* What manufacturing controls are necessary?

6. *Reference standards.* What reference products and/or reference standards are necessary and available? The United States Pharmacopeial (U.S.P.) Convention is in the process of setting new standards for exocrine pancreatic insufficiency drug products, and a U.S.P. reference standard is not currently available. What criteria are needed to establish an appropriate U.S.P. reference standard?

7. *Enzyme content and labeling.* What is the best way to assure consistency of actual enzyme content per dosage unit versus the amount declared in the product labeling? What product limits (not less than and not more than) should be allowed?

8. *Dissolution rates.* How can dissolution rates and in vivo bioavailability of the drug in the gut be measured? What is the correlation of the drug's release and activity with its dissolution profile?

In view of the many questions associated with exocrine pancreatic insufficiency drug products, the agency has concluded, under 21 CFR 10.65, that it would be in the public interest to hold a workshop to discuss these issues.

The agency requests information on the above questions from any interested person. Any individual or group wishing to submit data relevant to the questions above prior to the workshop should send them on or before April 10, 1992 to Docket No. 79N-0379, Dockets Management Branch (address above). Any individual or group wishing to make a presentation at the workshop should contact Helen Cothran or Diana Hernandez, Division of OTC Drug Evaluation (HFD-210), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8888. Interested persons who wish to participate must also send a notice of participation on or before April 10, 1992 to the Dockets Management Branch (address above). All notices submitted should be identified with the docket number found in brackets in the heading of this document and should contain the following information: Name; address; telephone number; business affiliation, if any, of the person desiring to make a presentation; and the subject and approximate amount of time requested for the presentation.

Groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. After reviewing the notices of participation, FDA will notify each participant of the schedule and time allotted to each person.

The administrative record for the rulemaking for OTC exocrine pancreatic insufficiency drug products is being reopened to include all comments and data submitted since the record previously closed on November 12, 1991, and the proceedings of this workshop. The administrative record will remain open until July 23, 1992, to allow comments on matters raised at the workshop.

References

(1) Letter from R. Beall, Cystic Fibrosis Foundation, to S. Fredd, FDA, August 15, 1991, Comment No. C213, Docket No. 79N-0379, Dockets Management Branch.

(2) Letter from R. Beall, Cystic Fibrosis Foundation, to S. Fredd, FDA, September 16, 1991, Comment No. C213, Docket No. 79N-0379, Dockets Management Branch.

(3) Letter from R. Beall, Cystic Fibrosis Foundation, to Dockets Management Branch, October 21, 1991, Comment No. C203, Docket No. 79N-0379, Dockets Management Branch.

(4) Memorandum of meeting between Cystic Fibrosis Foundation and FDA, November 26, 1991, coded MM 1, Docket No. 79N-0379, Dockets Management Branch.

(5) Letter from R. Beall, Cystic Fibrosis Foundation, to S. Fredd, FDA, January 13, 1992, Comment No. Docket No. 79N-0379, Dockets Management Branch.

Dated: March 4, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-5691 Filed 3-10-92; 8:45 am]

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Health Care Financing Administration

42 CFR Part 411

[BPD-674-P]

RIN 0938-AF40

Medicare Program; Physician Ownership of, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: The proposed rule would incorporate into regulations the provisions of section 6204 of the Omnibus Budget Reconciliation Act of 1989, as amended by section 4207(e) of the Omnibus Budget Reconciliation Act of 1990, which provide that, if a physician or a member of a physician's immediate family has a financial relationship with an entity, the physician may not make referrals to the entity for the furnishing of clinical laboratory services under the Medicare program, except under specified circumstances.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 11, 1992.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-674-P, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

Due to staffing and resource limitations, we cannot accept audio or video comments or facsimile (FAX) copies of comments. In commenting, please refer to file code BPD-674-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone : (202) 245-7890).

If you wish to submit comments on the information collection requirements contained in this proposed rule, you may submit comments to: Allison Herron, HCFA Desk Officer, Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the Federal Register containing this document, send your request to the Government Printing Office, ATTN: New Order, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 512-2250. The cost for each copy (in paper or microfiche form) is $1.50. In addition, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register.** The order desk operator will be able to tell you the

benefit made directly or indirectly, overtly or covertly, in cash or in kind.

C. General Prohibition on Referrals.

In § 411.353(a), we propose that, unless otherwise permitted under an exception, a physician who has a financial relationship with an entity (or who has an immediate family member who has a financial arrangement with an entity) may not make a referral to that entity for the furnishing of clinical laboratory services under Medicare beginning January 1, 1992.

The revised Federal requirements for laboratories and laboratory services located at 42 CFR part 493 were published as a final rule on March 14, 1990 (55 FR 9538), and became effective September 10, 1990 (except with respect to participation in proficiency testing, which became effective January 1, 1991). Section 493.2 of the March 1990 regulations defines a "laboratory" as "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or implement of, or the assessment of the health of, human beings. These examinations also include screening procedures to determine the presence or absence of various substances or organisms in the body." Thus, a referral to an "entity furnishing clinical laboratory services" would, for purposes of section 1877, be a referral to an entity furnishing the services described in § 493.2.

This definition includes furnishing anatomic laboratory services. However, it would not include non-invasive tests, such as electroencephalograms (EEGs) or electrocardiograms (EKGs), nor would it include x-rays or diagnostic imaging services, such as mammograms and computerized axial tomography (CAT) scans.

A financial relationship may be through ownership, investment, or a compensation arrangement between the entity and the physician or physician group or an immediate family member of the physician. Furthermore, an ownership or investment interest may be through equity, debt, or other means.

We emphasize several points concerning this general prohibition. First, while some of the terms used in section 1877 (for example, "fair market value") are similar to those contained in the final rule published by the OIG on July 29, 1991 (56 FR 35952) to implement section 1128B(b) (the anti-kickback statute), the two sets of rules are independent of each other and have different ramifications.

Section 1128B(b) contains criminal penalties applicable to individuals or entities that solicit or receive remuneration in return for referring individuals for covered services, and for offering or paying remuneration to induce persons to make referrals for covered services. The regulations of the OIG (codified at 42 CFR 1001.952) describe various payment practices that, although falling within the statutory language of section 1128B(b), would be protected from prosecution. The practices described in the OIG rule are referred to as "safe harbors." Section 1877 does not prohibit any financial relationship; instead, it prohibits referrals and payment for clinical laboratory services when certain relationships exist. This proposed rule is independent of the OIG final rule, and providers and physicians will need to examine ownership, compensation, and practice arrangements within the scope and objectives of each separate rule.

Second, the general prohibition on referrals would apply only to referrals for clinical laboratory services that would otherwise be covered by the Medicare program. Therefore, referrals for clinical laboratory services to be furnished for a physician's non-Medicare patients are not affected by section 1877 or this proposed rule.

Third, a physician who has no financial relationship with a clinical laboratory (other than his own office laboratory) would not be affected by this proposed rule unless he or she is ordering clinical laboratory services under a consultation request from another physician who has a financial relationship with the laboratory, or he or she is participating in a "contravention scheme" as described in section 1877(g)(4).

For purposes of Medicare coverage, a "consultation" is a professional service furnished to a patient by a physician (the consultant) at the request of the patient's attending physician. A consultation includes the history and examination of the patient as well as a written report that is transmitted to the attending physician for inclusion in the patient's permanent record. If, in the course of that consultation, the consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring physician has a financial interest. Therefore, when a physician refers a patient for a consultation, it would be prudent for the referring physician to provide to the consultant a list of laboratories from which the consulting physician should not order services.

Other referrals, such as sending a patient to a specialist who assumes responsibility for furnishing the appropriate treatment, or providing a list of referrals for a second opinion, are not "consultations" or "referrals" that would trigger the laboratory services use prohibition. However, if two or more physicians enter into an agreement described in section 1877(g)(4) as a "circumvention scheme" to indirectly avoid the prohibition on referrals, they would be subject to a civil money penalty of up to $100,000.

For purposes of identifying financial relationships that may trigger the statutory prohibition on referrals under Medicare, we propose to adopt the description of ownership, investment, and compensation arrangements contained in sections 1877(a)(2) and (h)(1) of the Act. These provisions state that financial relationships include ownership and investment interest, which may be through equity, debt or other similar means, as well as compensation arrangements, which are any arrangements involving remuneration between the parties. If a financial relationship exists, the physician may not make referrals to the entity for otherwise covered clinical laboratory services, and the entity may not bill the Medicare program or any other person for services furnished under a referral, unless the relationship falls within one of the statutory exceptions.

We propose to include indirect financial relationships in the statutory prohibition on referrals under Medicare. A physician would be considered to have an indirect financial relationship with a laboratory entity if he or she had an ownership interest in an entity, which in turn has an ownership interest in the laboratory entity.

We do not intend to exempt a financial relationship that is entered into in order to comply with section 1877 if it would not qualify under one of the statutory exceptions. For example, assume that a laboratory has been owned by a group of physicians for 15 years and the physicians enter into an agreement with a third party to sell the laboratory before the January 1, 1992 effective date of the referral prohibition, for a fixed price, with installment payments being made to the physicians through 1996. Unless one of the exceptions listed in section 1877 applies (for example, the laboratory is in a rural area), the physicians would be precluded under section 1877(a) (and proposed § 411.353) from making

referrals to the laboratory for clinical laboratory services that would otherwise be covered by Medicare, effective January 1, 1992.

Thus, a sales agreement that predates the January 1, 1992 effective date of the referral prohibition but provides for a continuing financial relationship through installment payment would operate to preclude the physician from making referrals to the entity for Medicare clinical laboratory services until all payments are completed. Physicians who are receiving installment payments from the sale of their laboratory would retain an incentive to refer business to the laboratory to maintain the financial viability of the laboratory. A "debt" relationship does not expire with the signing of an instrument that establishes the debt; it expires when the debt has been fully paid. Nor does a mere change in the form of the debt, such as changing an open account to a promissory note, extinguish the debt. We believe a loan from a physician to an entity, or from an entity to a physician, would raise the possibility that referrals would be for the purpose of ensuring returns on the investment, and these referrals would be prohibited unless one of the statutory exceptions applies.

Similarly, a financial relationship between a physician and an organization related to the entity that furnishes clinical laboratory services (for example, a parent or subsidiary corporation of the entity) would also be covered by these regulations as an indirect financial relationship with the entity. Therefore, entering into an agreement under which an organization related to an entity agrees to pay the entity's debt to a physician would not end the financial relationship between the entity and the physician for purposes of the proposed regulations. The physician would continue to have a financial relationship with the entity through the related organization until the debt were paid. Also, if a physician were to sell his or her interest in a laboratory to an organization related to the laboratory, and that related organization agrees to pay the physician over an extended period of time for the laboratory interest, the physician's financial relationship with the entity is continuing, and he or she may not make referrals to the laboratory for Medicare-covered services until the debt is fully paid. Moveover, the fact that a debt is nonrecourse or unsecured would not alter this conclusion.

Finally, section 1877(b)(5) defines permissible exceptions other than those specified in section 1877 as any "financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." We solicit comments delineating financial relationships that would comply with this statutory definition.

In § 411.353(b), we state that an entity that furnishes clinical laboratory services under a prohibited referral could not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payor, or other entity for the clinical laboratory services performed under that referral. For example, there are certain circumstances where Medicare benefits are secondary to benefits payable by another third party payor, such as an employer group health plan for employed individuals or the spouses of employed individuals. Under section 1877(a)(1)(B) and proposed $411.353(b), an entity that furnishes clinical laboratory services under a prohibited referral may not bill the employer group health plan for the services.

In accordance with section 1877(g), proposed § 411.353(c) provides that Medicare payment would not be made for a clinical laboratory service that is furnished under a prohibited referral.

Proposed § 411.353(d) would require an entity that collects payment for a laboratory service that was performed under a prohibited referred to refund all amounts collected on a timely basis.

The following sections discuss the specific exceptions. While certain ownership or investment interests would not trigger the section 1877 prohibition on referrals, physicians who have these interests may also have compensation arrangements with the entity that may operate to preclude referrals by the physician to the entity for clinical laboratory services under other provisions of section 1877.

D. Exceptions that Apply to Specific Services

In accordance with section 1877(b), the prohibition on clinical laboratory referrals would not apply if the following conditions are met:

1. Physicians' Services in Group Practice

In § 411.355(a), we propose that a referral for physicians' services furnished personally by (or under the direct personal supervision of) a physician who is in the same group practice as the referring physician is not a prohibited referral. Under this exception, the referring physician and the consulting or diagnosing physician must be in a group practice that meets the requirements of section 1877(h)(4) and proposed § 411.350. Under this exception, the clinical laboratory services that are treated as physicians' services for payment purposes would be allowed if they are furnished directly by the consulting physician and performed in the group's laboratory.

The following clinical diagnostic laboratory services are treated as physician services for payment purposes and could be the subject of referrals under this exception:

CPT Code	Description
80500–80502	Clinical pathology consultation.
85095–85109	Codes dealing with bone marrow smears and biopsies.
86077–86079	Blood bank services.
88000–88125	Certain cytopathology services.
88160–88199	Certain cytopathology services.
88300–88399	Surgical pathology services.

These services are listed in the Current Procedural Terminology, 4th Edition, (copyrighted by the American Medical Association (1991)) and listed in section 5114.1.B. of the Medicare Carriers Manual (HCFA Pub. 14–3).

Since the law requires the services to be performed personally by a group practice physician, the service would be required to be performed in the group practice's office. On the other hand, the consulting physician could not refer the laboratory work to another entity with which the group has a financial relationship unless the group practice physician personally furnished the physician services performed at the other entity.

In this context we recognize that practical relationships may exist among physicians that involve shared office space and shared laboratory facilities and services that are not accommodated by the in-office ancillary services exception under section 19877(b)(2). For example, two (or more) physicians may share a suite including a laboratory used only to furnish services for their patients, but the physician's financial arrangement may not meet the strict definition of a "group practice" (section 1877(h)(4)). Unless an exception is developed, referrals by these physicians to the shared laboratory (that is, an in-office laboratory in which the individually practicing physicians all have ownership interest or for which each physician shares in the operating costs) would be prohibited.

We are not certain of the extent to which these arrangements exist, or whether any arrangements warrant the promulgation of an additional exception under section 1877. Therefore, we invite public comments about these issues and solicit suggestions about whether (and if so, how) to formulate an additional

exception to address business or practice arrangements involving shared office space that would not pose a risk of program or patient abuse.

2. In-office Ancillary Services

In § 411.355(b), we propose that a referral for in-office laboratory services would not be considered a prohibited referral under the following conditions:

• Performance Requirements.

The laboratory services must be performed personally by one of the following: (1) The referring physician; (2) a physician who is a member of the same group practice as the referring physician; or (3) a non-physician employee of the referring physician or group practice. When a laboratory service is performed by a non-physician employee, it must be performed under the direct supervision of the employing physician or a physician in the group practice.

• Location Requirements.

The in-office laboratory services must either be furnished in a building where the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services; or a building that is used by the group practice for centrally furnishing the group's clinical laboratory services (if the referring physician is a member of the group practice).

• Billing Requirements.

The in-office laboratory services must be billed by the physician who performed or supervised the laboratory services, or by the group practice in which the physician is a member, or an entity that is wholly owned by the physician or physician's group practice.

In contrast, a laboratory that is shared by several physicians who are independent practitioners and who are not members of a group, as defined in section 1877(h)(4), would not qualify for this exception. For example, physicians who are not engaged in the group practice of medicine may have entered into a partnership for furnishing laboratory services to their individual practices. The partnership entity is furnishing the services. Under section 1833(h)(5), the partnership must submit Medicare claims and receive Medicare payment in its name for the laboratory services. Thus, the partnership laboratory would have to obtain a provider number for this purpose. A referral by one of the physician partners in these circumstances would be considered a prohibited referral under section 1877.

3. Services Furnished to Prepaid Health Plan Enrollees

In § 411.355(c), we propose that referrals for services within certain prepaid health plans would not be prohibited referrals. Section 1877(b)(3) specifies that the services must be furnished by one of the following organizations to an individual who is enrolled in the organization:

• A health maintenance organization or a competitive medical plan in accordance with a contract with us under section 1876.

• A health care prepayment plan in accordance with an agreement with us to furnish the services to Medicare beneficiaries under section 1833(a)(1)(A).

• An organization that is receiving payments on a prepaid basis for the enrollees under a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

This exception would apply only with respect to services that are furnished by the organization to individuals who are enrolled in the prepaid health plan in accordance with the organization's Medicare contract or agreement under one of the specified statutory authorities. Services that these organizations may provide to members or non-members outside the context of the Medicare contract or agreement would not be covered under this exception.

E. Exceptions for Certain Ownership or Investment Interests

1. Publicly Traded Securities

We propose in § 411.357(a) that the prohibition on referrals by interested investors would not apply if the financial relationship results from the ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that are purchased on terms generally available to the public and are in a corporation that—

• Is listed for trading on the New York Stock Exchange, the American Stock Exchange, or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; and

• Had, at the end of the corporation's most recent fiscal year, total assets exceeding $100,000,000.

In this proposal, the first prerequisite to qualify for protection is that the stocks must be purchased on terms generally available to the public, as specified in section 1877(c). This means that the general public must have the same opportunity to buy and sell the stock as the physician investors. For example, the following scenario would not qualify for this exception. A joint venture laboratory merges into a new corporation, the existing partners swap partnership shares for stock, the stock then starts to be traded publicly and the corporation reaches the $100 million asset level. On face value, the investment interest appears to qualify for the exception because the corporation has $100 million in assets. However, because the ex-partners bought their shares through a transaction before the stock was offered to the general public, the pre-requisite that the stocks be purchased on terms generally available to the public would not be met.

Under the statute and the proposed regulations, the $100 million in assets requirement applies only to the corporate entity that furnishes the clinical laboratory services. That is, the assets of a related corporation (for example, a parent, subsidiary, or sister corporation) could not be considered for purposes of qualifying the laboratory entity under the $100 million asset test. Furthermore, we are proposing that a corporation's total assets would not include assets obtained primarily for the purpose of meeting the $100 million asset test of this exception. For example, an entity may have a number of purposes in acquiring assets, but a violation may be proved by showing that no other purpose is more significant than the desire to qualify for this exception. We are proposing this criterion because we do not believe Congress intended to protect entities with $100 million in assets when those assets are not obtained in the normal course of business but are acquired primarily for the purpose of qualifying for this exception. We are proposing this additional element concerning the acquisition of assets under the Secretary's general authority of section 1102(a), which states that the Secretary may promulgate regulations for the efficient administration of the program. We believe this element is necessary for the efficient administration of the Medicare program because it attempts to block those arrangements that would clearly be a circumvention of the law through "sham" transactions.

We are specifically interested in receiving suggestions from the public about these proposals and other effective ways of protecting against program and patient abuse in this area.

2. Specific Providers

In § 411.357(b), we propose that the prohibition on referrals by interested investors would not apply if the financial relationship results from ownership or investment in the following providers:

A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area, as that term is defined in § 412.62(f)(1)(ii)) and that meets the following conditions:

—The laboratory testing that is referred by a physician owner or investor must either—

—Be performed on the premises of the rural laboratory; or

—If not performed on the premises, the laboratory performing the testing must bill the Medicare program directly for the testing.

—The majority of tests referred to the rural laboratory must be referred by physicians who have office practices located in a rural area. "Urban area" means—

—A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Office of Management and Budget; or

—The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21, 42 U.S.C. 139ww (note)): Litchfield County, Connecticut; Sagadahoc County, Maine; York County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

As noted, to supplement the statutory provision concerning services furnished in a "rural laboratory", we are proposing two requirement intended to address possibility that this exception would be misused. We believe, in enacting this exception, Congress intended to benefit Medicare beneficiaries who live in rural areas where laboratories may not otherwise be available wthout the financial support of local physicians. We are concerned, however, about the possibility that physicians who have an ownership interest in an urban laboratory (and are precluded from making Medicare referrals to it) may set up a storefront or "shell" laboratory with a rural address in order to gain the benefit of this exception. In this scenario, the urban physician owner would make referrals to the rural laboratory, which would in turn refer the tests to the urban laboratory in which the physician also has an ownership interest. Alternatively, urban laboratories with physician owners could set up laboratories in rural areas for the purpose of performing tests referred by the physician owners for their urban patients.

To prevent these possible abuses and help assure that the rural laboratory exception benefits rural beneficiaries, we are proposing to require, when physician owners or investors make referrals to a laboratory located in a rural area, that the tests be performed directly by the laboratory on its premises, or if referral to another laboratory is necessary, that tests be billed by the laboratory that performs the test. Because an urban laboratory may not bill for services referred by a physician owner (unless another exception applies), these additional criteria should discourage the circumvention schemes described above.

Secondly, we propose to add the requirement that majority (at least 51 percent) of the tests referred to the rural laboratory are referred by physicians who have office practices in a rural area. (For purposes of this provision, we would apply the definition of "practice" set forth in proposed new § 411.351, as described below in the discussion of rental and leasing of office space.) This requirement should help to assure that the laboratory is in fact serving rural beneficiaries, and is not simply located in the rural area for the purpose of furnishing services referred by urban owners for their urban patients. In addressing this potential problem, we considered the alternative of requiring that at least 85 percent of the tests performed by the rural laboratory be for beneficiaries who reside in rural areas. However, based on our concern that compliance with this requirement could be administratively difficult and overly burdensome for rural laboratories, we opted against proposing this criterion. Nonetheless, we are speifically interested in receiving suggestions from the public about this matter, about our proposed requirements, and about other effective ways of protecting against program or patient abuse in application of the rural provider exception set forth in section 1877(d)(2).

Since the Secretary has the authority to promulgate regulations for the efficient administration of the program, we believe it is appropriate to require that a rural laboratory operate as a full service laboratory, not a shell laboratory, that is available to furnish laboratory services to patients residing in the rural area. Finally, we believe the additional proposed requirements are consistent with the legislative intent of section 1877 and are necessary to preclude circumvention of the statute.

In addition, the prohibition on referrals by interested investors would not apply if the ownership or investment interest is in the following providers:

A hospital located in Puerto Rico.

A hospital located outside of Puerto Rico if one of the following conditions is met:

—The referring physician is authorized to perform patient care services at the hospital and the physican's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital, such as the laboratory (as provided in section 1877(d)(3)).

—The referring physician's financial relationship with a hospital does not relate to the furnishing of clinical laboratory services (as provided in section 1877(b)(4)).

Examples of the section 1877(b)(4) exception to the prohibition on referrals would include the following:

A group of physicians contracting with a hospital to furnish emergency room services and receiving payment from the hospital under a guaranteed free arrangement.

• A group of physicians owning and operating a free-standing mobile CAT scanner, which a hospital utilizes for its patients and pays the group for the use of the equipment.

F. Exceptions for Certain Compensation Arrangements

We propose to add § 411.359 to specify that, for purposes of the referral prohibition, a compensation arrangement (as defined in proposed § 411.351) would not include the following arrangements:

1. Rental or Lease of Space

In § 411.359(a), we would exempt the rental or lease of space by a lessee to a lessor if a written agreement is signed by the parties, which sets forth a term of at least 1 year, identifies the premises covered by the lease or rental agreement and specifies the space dedicated for use by the lessee, and provides for payment on a periodic basis of an amount that is consistent with the fair market value of the rented or leased premises in arm's-length transactions. If the agreement is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the full term of the agreement, we would require that the agreement specify exactly the schedule of the intervals, their precise length, and the exact rent for the intervals. The agreement would have to provide for aggregate payments that do not vary (directly or indirectly) based on the

volume or value of any referrals generated between the parties for clinical laboratory services. Finally, the lease agreement would have to be considered to be commercially reasonable even if no referrals are made between the lessee and the lessor.

If a laboratory entity rents or leases office space in which an interested investor (either a physician or immediate family member) has an ownership or investment interest, an additional condition must be met to qualify for an exception. In § 411.359(a)(2), we propose that in addition to meeting the requirements described in proposed § 411.359(a)(1), the rented or leased office space must be in the same building as the building in which the physician (or the physician's group practice) has a practice. When one party is in a position to make referrals to another party, even if there is no explicit or implicit understanding regarding referrals, certain rental payments could be construed to induce referrals. Typically, these arrangements would involve rental payments either substantially in excess of or below the fair market value of the rental space. Accordingly, one fundamental principle underlying these exceptions is that the payment must be based on the fair market value, regardless of whether the payment is for space rental, personal services, or management contracts.

The condition concerning maintenance of a practice is specified in the statute at section 1877(e)(1)(B). By use of the phrase "a practice", we believe Congress did not intend, on the one hand, that this standard could be met by an insignificant portion of the physician's professional performance occurring in the building. On the other hand, we realize that many physicians conduct their professional services in different locations; that is, a physician might have two offices in which he or she diagnoses and treats patients and where records are kept and office staff furnish patient services and perform overall administrative matters. Accordingly, we are proposing to include in § 411.351 a definition of "practice" to mean an office in which the physician, as a matter of routine, regularly sees patients for purposes of diagnosis and treatment and where patient records are kept. Comments about the scope of this definition are requested.

Also, in addition to the statutory requirements that set forth certain standards and safeguards for rental and lease arrangements, we are proposing a requirement concerning use of space for periodic intervals. We believe it is necessary to require that the periodic intervals be established in advance and be specified in the lease or rental agreement, rather than allowing the intervals to vary week-to-week on the basis of the number of referred patients to be serviced at the premises.

We are proposing these two additional standards under the Secretary's authority, as specified in section 1877(e)(1)(C), to identify additional safeguards to protect against program or patient abuse.

2. Certain Employment and Service Arrangements With Hospitals

We propose in § 411.359(b) that an arrangement between a hospital and a physician (or an immediate family member) for the employment of either the physician or family member or for the provision of administrative services will not be considered a compensation arrangement for purposes of the referral prohibition under the following conditions:

- The arrangement is in writing and specifies the day-to-day services to be furnished by the physician or immediate family member and is signed by the parties.
- The amount or value of the remuneration to the physician or immediate family member is consistent with the fair market value of services in arm's-length transactions, and is not determined in a manner that varies (directly or indirectly) based on the volume or value of any referrals of business otherwise generated by the physician.
- Finally, all terms of the arrangement must be considered commercially reasonable even if no referrals are made to the hospital.

3. Physician Recruitment

We propose in § 411.359(d) that, for purposes of the referral prohibition, remuneration provided by a hospital to a physician that is intended to induce the physician to relocate to the geographic area served by the hospital to become a member of the hospital medical staff would not be considered a compensation arrangement under the following conditions:

- The arrangement and its terms are in writing and signed by both parties.
- The hospital does not condition the agreement on the physician's referral of patients to the hospital.
- The hospital does not vary (directly or indirectly) the amount or value of the remuneration based on volume or value of any referrals the physician generates for the hospital.
- The hospital does not restrict the physician from establishing staff privileges at another hospital or referring business to another entity.

While these requirements for the most part follow the statute, we have used the discretion authorized by section 1877(e)(4)(C) to propose additional requirements. For the reasons stated earlier, we believe it is appropriate to require physician recruitment arrangements to be set out in writing and signed by the parties. Also, we believe it is appropriate to assure that the arrangement permits a physician to establish staff privileges at hospitals other than the one with which an arrangement has been made.

4. Isolated Transactions

We propose in § 411.359(e) that an isolated financial transaction, such as a one-time sale of property, would not be considered a compensation arrangement for purposes of section 1877 if it meets the following conditions:

- The transaction is in writing and signed by the parties.
- There is no financial relationship between the entity and the physician of 1 year before and 1 year after the transaction.
- The amount or value of remuneration for the transaction is—
  - —Consistent with the fair market value of services in arms-length transactions; and
  - —Not determined in a manner that varies (directly or indirectly) based on the volume or value of any referrals of business that may be generated by the physician or the immediate family member.
- The remuneration is provided under an arrangement that would be considered commercially reasonable even if no referrals were made.

We are proposing the additional element concerning the 1-year period under the authority of section 1877(e)(5)(B), which states that the transaction meets all other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse. We believe this element is necessary to assure that both the transaction as well as the existing relationship are isolated.

5. Service Arrangements With Entities Other Than Hospitals

We propose in § 411.359(c) that the following arrangements between a physician and an entity other than a hospital would not be considered a compensation arrangement for purposes of the referral prohibition:

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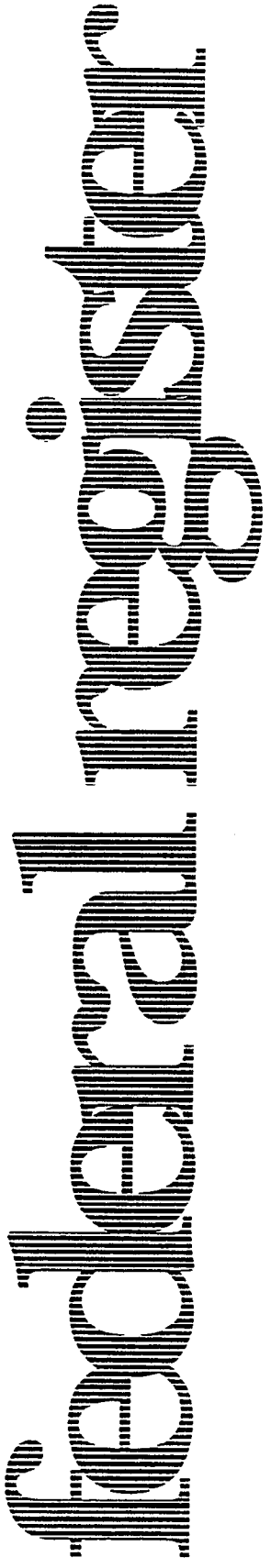

Monday
August 14, 1995

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 411

Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services; Financial Relationship Reporting Requirements: Final Rule

§ 411.356(b)(1). Note that, as discussed elsewhere in the preamble, unless the group practice that owns the laboratory satisfies the definitional requirements, referrals by group practice physicians to the laboratory might also be called into question.

8. Practice

In the proposed rule (411.351), we defined a "practice" to mean an office in which the physician, as a matter of routine, sees patients for purposes of diagnosis and treatment and where patient records are kept.

Comment: One commenter indicated that many group practices provide medical services in satellite facilities where only limited medical services are offered and that the medical records of the group practice are kept in a centralized location. Thus, the commenter recommended that we clarify in the final rule that the definition of "practice" is not incorporated into the definition of "group practice."

Another commenter stated that some physicians maintain a medical practice without being tied to a particular location, such as certain hospital-based physicians and those who treat nursing home patients. These physicians use office space only to receive mail and for other administrative support functions. Such a practice, be it group or individual, does not have an office for purposes of diagnosis and treatment, or even to keep substantial amounts of medical records. The commenter believed this fact is not taken into account in the definition.

Response: We acknowledge that the commenters have raised some legitimate problems with the proposed approach and how difficult it is to determine where someone has a "practice." We are responding to these comments by creating a new, more equitable standard that is not based on the concept of a physician's "practice" (and thus eliminate the definition from the rule). We are using the new standard required by OBRA '93, which states that to qualify as a rural provider, substantially all of the clinical laboratory services furnished by the entity must be furnished to individuals residing in the rural area. As part of this standard, we are defining "substantially all" as meaning that 75 percent of the individuals to whom services are furnished reside in the rural area. Although the effective date of this provision for rural providers is January 1, 1995, we believe it is reasonable to incorporate it into this final rule.

9. Referral

In the proposed rule (§ 411.351), a "referral" means either of the following:

- The request by a physician for, or ordering of, any item or service for which payment may be made under Medicare Part B, including a request for a consultation with another physician other than a pathologist, and any test or procedure ordered by or to be performed by (or under the supervision of) that physician; or
- If a plan of care includes the performance of clinical laboratory testing, the request or establishment of the plan of care by a physician. When a pathologist, in responding to another physician's request for a consultation, furnishes or supervises the furnishing of clinical diagnostic laboratory tests and pathological examination services, the services are not considered to have been furnished on a referral basis.

a. Pathology Referrals

Comment: Two commenters wanted the definition of "referral" to be clarified so as to exclude circumstances in which a pathologist providing professional services to one laboratory sends specimens ordered by the attending physician to a second laboratory in which the pathologist has a financial interest.

One commenter indicated that the definition should also exclude circumstances in which a pathologist recommends to an attending physician appropriate follow-up laboratory services.

Response: Under the definition of "referral" in section 1877(h)(5), a request by a pathologist for clinical diagnostic laboratory tests and pathology examination services will not be considered a referral if such laboratory services are furnished by (or under the supervision of) the pathologist as a result of a consultation requested by another physician. Thus, if the pathologist described in the first comment either performs or directly supervises the performance of the laboratory testing in the second laboratory, the request for services would not be considered a referral by the pathologist. The answer is different, however, if the pathologist sends laboratory work to a laboratory with which he or she has a financial relationship and the services are not performed by the pathologist or under his or her direct supervision. The services in this situation would be considered to have been furnished as a result of a prohibited referral, unless one of the exceptions applies. Similarly, if the pathologist sends tests to a laboratory with which the first referring physician has a financial relationship, the referral would be prohibited, unless an exception applies. Because we recognize that there are situations in which a physician's request for a consultation with a pathologist could constitute a referral, this final rule revises the proposed definition of "referral" by removing the phrase "other than a pathologist".

We do not consider a pathologist's recommendation to the attending physician for additional testing to be a referral. That is because it is the attending physician who ultimately decides whether such testing is necessary and whether to order the additional testing and from what laboratory.

b. Plan of Care and End-Stage Renal Disease (ESRD) Patients

Comment: One commenter indicated that the proposed rule is ambiguous with regard to the "plan of care" element within the definition of "referral." At one level, the commenter believed, the language is simply unclear in that, with regard to "a plan of care that includes the performance of clinical laboratory tests," it is difficult to understand what is meant by the "request or the establishment of the plan of care by a physician." According to the commenter, this might mean that when a physician establishes a plan of care that entails laboratory testing and the facility or other individual implementing the plan of care orders those tests from a laboratory, the physician shall be considered to have made the laboratory referral. If this interpretation is correct, the commenter believed there are some issues specific to chronic hemodialysis facilities and referrals that require clarification.

The commenter wrote that hemodialysis patients receive three different classes of clinical laboratory tests:

1. Tests ordered on a patient-specific basis on account of particular clinical signs and symptoms and referred by the dialysis facility to an independent or hospital-based clinical laboratory that bills Medicare. These tests pose no interpretive problems, as the physician does, in fact, order each one individually.

2. Routine monthly testing applicable to every patient and for which payment is incorporated into the facility's dialysis composite rate.

3. Testing integral to monitoring the patient during the dialysis treatment itself, performed in the facility and not billed separately.

The commenter pointed out that every time a patient is referred to a facility for chronic renal dialysis, clinical laboratory testing from categories 2 and 3 is required on an ongoing basis as part of the overall care of the patient. If the physician's plan of care for dialysis is deemed to include these tests for purposes of this rule, the commenter believed that the practical result would be to prohibit physicians from making referrals for tests to dialysis facilities in which they have an ownership interest.

A second commenter stated that the ESRD program includes in its composite rate payment methodology most items and services related to the treatment of patients with ESRD, including hematocrit and hemoglobin tests, clotting time tests, routine diagnostic tests, and routine diagnostic laboratory tests. Thus, the commenter pointed out, the determination of whether an item or service is included under the composite rate payment is presumptive and in no way depends on the frequency with which a dialysis patient requires the item or service. The commenter recommended that the final rule, or the preamble to the final rule, explicitly exclude clinical laboratory referrals covered by ESRD from its application.

Response: Section 1877(h)(5)(B) says that "the request or establishment of a plan of care by a physician which includes the provision of [clinical laboratory services] constitutes a "referral" by a "referring physician." The commenter has pointed out that this provision, carried over into the proposed rule, is ambiguous and unclear. The statute could mean (1) that there is a referral when a physician establishes a plan of care or requests that one be established that includes laboratory services or (2) that a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services constitutes a referral. Because the comments reveal that this provision has caused confusion, we have decided to adopt the latter interpretation and have incorporated it into the regulation.

We also agree that it is not clear what technically constitutes a "plan of care." We believe that any time a physician orders any item, service, or treatment for a patient, that order is pursuant to a plan of care. If a plan of care entails laboratory testing and the facility or other individual implementing the plan orders those tests from a laboratory, the physician who established the plan of care is considered to have made the laboratory referral. In addition, as we mentioned in a previous response, the prohibition could also apply if the individual implementing some or all of the plan of care is a consulting physician. We agree, however, that, under certain circumstances, this may cause problems when those laboratory tests are included in the ESRD composite rate. Thus, as we discuss below, we are including those laboratory tests that are paid under the ESRD composite rate as part of a new exception. We agree that the application of the composite rate constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered.

c. Consultation Referrals

Comment: A few commenters believed that it was unnecessary for us to include in the preamble the discussion about consultations (57 FR 8595) and the responsibility of a consulting physician to not engage in a cross-referral arrangement. They believed there is no corresponding statutory or regulatory provision and that, except for a small number of truly "bad apples" practicing medicine, physicians have not and will not engage in the complicated and tortuous process of directing referrals.

One commenter was concerned that the proposed rule suggests that physicians who refer to consultants have some obligation to tie the consultant's hands when it comes to which clinical laboratories the consultant can use. The commenter believed such an obligation runs afoul of the principle of medical ethics that requires a physician to refer patients to the entity that furnishes the most efficacious service, regardless of other considerations. The commenter indicated that, in a managed care setting, it may be impossible for the attending physician to even know who the consulting physician is, much less be in a position to dictate which laboratory is selected. In sum, this commenter believed that it will be difficult in practice for physicians to determine where the prohibition ends.

Response: We do not agree with these commenters. In response to the first comment, the discussion in the proposed rule was based on the statute at section 1877(g)(4). This provision says that "any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of [section 1877], shall be subject to a civil money penalty * * *."

Because the provision applies to physicians who make referrals and to "other entities," we believe that it can apply to consulting physicians who help a physician indirectly make prohibited referrals. In the preamble of the proposed rule (57 FR 8595) we stated that, if a consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring physician has a financial interest. We included this explanation to give the reader an example of the kinds of referrals that are prohibited under the statutory definition of "referral." Under section 1877(h)(5)(A), a request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by or performed under the supervision of that other physician) constitutes a referral. Thus, it is necessary for the consulting physician to be aware of any financial relationships the referring physician may have with a laboratory, in order for the referral not to be prohibited. Finally, the consulting physician is also obligated not to refer laboratory testing to an entity with which he or she has a financial relationship, unless an exception applies.

Concerning services furnished in a managed care setting, section 1877(b)(3) provides a general exception for services provided to patients enrolled in the prepaid health plans listed in that provision and in the regulations at §411.355(c).

d. Statutory Authority

Comment: One commenter noted that the statutory definition of referral encompasses requests for any item or service for which payment may be made under Medicare Part B, but the prohibition contained in the statute is aimed at referrals for clinical laboratory services and not other referrals. Thus, in the commenter's view, the statute makes the rule somewhat confusing. That is, the behavior that the statute seeks to restrict, referrals for clinical laboratory services, is narrower in scope than the behavior of "referring" itself. Therefore, the commenter suggested that the final rule clarify that the prohibited behavior is related to clinical laboratory services.

Response: We agree that the definition of "referral" under the statute at section 1877(h)(5) is broad. In section 1877(h)(5)(A), for physicians' services, it covers a physician's request for any item or service covered under Part B of

• We revised § 411.355 ("General exceptions to referral prohibitions related to both ownership/investment and compensation") to do the following:

+ For purposes of the in-office ancillary services exception in § 411.355(b), require that individuals furnishing services be "directly" supervised by the referring physician or by another physician in the same group practice. (The proposed rule had required that services be provided by an employee who was "personally" supervised by these physicians.)

+ Include among the locations where the service may be furnished a building that is used by the group practice for the provision of some or all of the group's clinical laboratory services. (The proposed rule had required that the building be used by the group practice for centrally furnishing the group's clinical laboratory services.)

• We added the following services to the general exceptions listed under § 411.355 ("General exceptions to referral prohibitions related to both ownership/investment and compensation"):

+ Services furnished by a qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act) to individuals enrolled in the organization (new § 411.355(c)(4)).

+ Services furnished in an ASC or ESRD facility or by a hospice and included in the ASC rate, ESRD composite rate, or per diem hospice charge, respectively (new § 411.355(d)).

• We revised proposed § 411.357, now designated as § 411.356, ("Exceptions to referral prohibitions related to ownership or investment interests") to—

+ Revise the requirements relating to publicly-traded securities, as specified in section 1877(c) of the Act (as amended by OBRA '93 and SSA '94), to include securities which "may be purchased" on terms generally available to the public, which can be those traded on additional stock markets, and which can be in corporations that had the following:

—Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding $100 million, or

—Stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years

+ No longer specify, with regard to the corporation's assets, that these assets must have been obtained in the normal course of business and not for the primary purpose of qualifying for the exception;

+ Expand the exception to include mutual funds that constitute ownership in shares in certain regulated investment companies, if the companies had, at the end of their most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

+ Until January 1, 1995, retained the exception for a hospital located outside of Puerto Rico based on the condition that the referring physician's ownership or investment interest does not relate to the furnishing of clinical laboratory services.

+ Revise the requirements relating to rural providers, as specified in the proposed rule, to delete paragraph (ii), which added the requirement that the majority of tests referred to the rural laboratory are referred by physicians who have office practices located in a rural area.

+ Revise the requirements relating to rural providers, as specified in the proposed rule, to include the requirement that substantially all of the tests furnished by the entity are furnished to individuals residing in a rural area.

• We revised proposed § 411.359, now designated as § 411.357, ("Exceptions to referral prohibitions related to compensation arrangements") to do the following:.

+ Revise (a)(1) to reflect new requirements specified by OBRA '93 for the rental of space.

+ Remove proposed paragraph (a)(2), which contained requirements related to a physician who has an ownership or investment interest in a laboratory and who also rents or leases space to the laboratory.

+ Add an exception for rental of equipment under certain conditions (new § 411.357(b)).

+ Add an exception for certain group practice arrangements with a hospital (new § 411.357(h).

+ Add an exception for payments by a physician to a laboratory or other entity in exchange for certain items and services (new § 411.357(i)).

+ Replace proposed § 411.359(b) ("Employment and service arrangements with hospitals") and proposed § 411.359(f) ("Salaried physicians in a group practice") with a new § 411.357(c) ("Bona fide employment relationships"). New § 411.357(c) is based on the exception at section 1877(e)(2) of the Act.

+ Replace proposed § 411.359(e) ("Service arrangements with non-hospital entities") with a new § 411.357(d) ("Personal service arrangements"). New § 411.357(d) is based on the exception at section 1877(e)(3) of the Act.

• We added a new § 411.360 that requires that a group practice submit annually a statement attesting that it met the "substantially all" test set forth, under the definition of "group practice," in § 411.351 of this rule. This section also specifies how a newly-formed group practice meets the "substantially all" criterion.

In addition to the above changes, we have made technical changes. For example, in proposed § 411.355(c)(1), we cross-referenced part 417, subpart C. Subpart C has been redesignated by a new rule. The applicable provisions being cross-referenced are now under subparts J through M. We have also made editorial changes that do not affect the substance of the provisions.

B. Interim Final Rule With Comment Period—Reporting Requirements for Financial Relationships Between Physicians and Health Care Entities That Furnish Selected Items and Services.

The interim final rule with comment published on December 3, 1991, is revised to incorporate the amendments to section 1877(f) made by SSA '94, to apply to any future reporting that we require. However, providers will not be held to the reporting requirements under section 1877(f) until we develop and issue the proper form and accompanying instructions booklet. Until that time, we will use audits and investigations as the primary tools to evaluate compliance with these provisions.

C. Source of Final Regulations.

Final regulations	Source
§ 411.1 Basis and scope	Proposed § 411.1.
§ 411.350 Scope of subpart	Proposed § 411.350, SSA '94.
§ 411.351 Definitions	§ 411.351.
Clinical laboratory services	Comments.
Compensation arrangement	Proposed § 411.352 and comments.
Direct supervision	Comments and OBRA '93.

program or to any individual, third party payer, or other entity for the clinical laboratory services performed under that referral.

(c) *Denial of payment.* No Medicare payment may be made for a clinical laboratory service that is furnished under a prohibited referral.

(d) *Refunds.* An entity that collects payment for a laboratory service that was performed under a prohibited referral must refund all collected amounts on a timely basis.

§ 411.355 General exceptions to referral prohibitions related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physicians' services,* as defined in § 410.20(a), that are furnished personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

(b) *In-office ancillary services.* Services that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.

(ii) A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member.

(iii) An entity that is wholly owned by the physician or the physician's group practice.

(c) *Services furnished to prepaid health plan enrollees by one of the following organizations:*

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M, of this chapter.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U, of this chapter.

(3) An organization that is receiving payments on a prepaid basis for the enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

§ 411.356 Exceptions to referral prohibitions related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be purchased on terms generally available to the public and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

(2) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding $100 million; or

(ii) Stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in § 412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

§ 411.357 Exceptions to referral prohibitions related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing and is signed by the parties and specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if

the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease are set in advance and are consistent with fair market value.

(5) The charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing and signed by the parties and specifies the equipment covered by the lease.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee.

(3) The lease provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(5) The lease would be commercially reasonable even if no referrals were made between the parties.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements*—(1) *General.* Remuneration from an entity under an arrangement to a physician or immediate family member of the physician, including remuneration for specific physicians' services furnished to a nonprofit blood center, if the following conditions are met:

(i) The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term of the arrangement is for at least 1 year.

(v) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled in the entity.

(ii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii) of the Act, the plan complies with any requirements the Secretary has imposed under that section.

(iii) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of paragraph (d)(2) of this section.

(3) Until January 1, 1995, the provisions in paragraph (d) (1) and (2) of this section do not apply to any arrangements that meet the requirements of section 1877(e)(2) or section 1877(e)(3) of the Act as they read before they were amended by the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66).

(e) *Physician recruitment.* Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(1) The arrangement and its terms are in writing and signed by both parties.

(2) The arrangement is not conditioned on the physician's referral of patients to the hospital.

(3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital.

(4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the conditions set forth in paragraphs (c)(2) and (c)(3) of this section are met with respect to an entity in the same manner as they apply to an employer. There can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions which are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* (1) Until January 1, 1995, any compensation arrangement between a hospital and a physician or a member of a physician's immediate family if the arrangement does not relate to the furnishing of clinical laboratory services; or

(2) Remuneration provided by a hospital to a physician if the remuneration does not relate to the furnishing of clinical laboratory services.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under

which clinical laboratory services are provided by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before December 19, 1989, and has continued in effect without interruption since then.

(3) With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with an agreement that is set out in writing and that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group.

(b) A newly-formed group practice (one in which physicians have recently begun to practice together) or any group practice that has been unable in the past to meet the requirements of section 1877(h)(4) of the Act must—

(1) Submit a written statement to attest that, during the next 12-month period (calendar year, fiscal year, or next 12 months), it expects to meet the 75-percent standard and will take measures to ensure the standard is met; and

(2) At the end of the 12-month period, submit a written statement to attest that it met the 75-percent standard during that period, billed for those services under a billing number assigned to the group, and treated amounts received for those services as receipts of the group. If the group did not meet the standard, any Medicare payments made for clinical laboratory services furnished by the group during the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier by December 12, 1995.

5. Section 411.361 is revised to read as follows:

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as HCFA specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.

(c) *Required information.* The information submitted to HCFA under paragraph (a) of this section must include at least the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician who has an immediate relative (as defined in § 411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if requested by HCFA).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary. Entities are given at least 30 days from the date of the carrier's or intermediary's request to provide the initial information. Thereafter, an entity must provide updated information within 60 days from the date of any change in the submitted information. Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to HCFA or the OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 for each day of the period beginning on the day following the applicable deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to HCFA under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 16, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: May 10, 1995.

Donna E. Shalala,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 411, 424, 435, and 455

[HCFA-1809-P]

RIN 0938-AG80

Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would incorporate into regulations the provisions of sections 1877 and 1903(s) of the Social Security Act. Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of designated health services under the Medicare program, unless certain exceptions apply. The following services are designated health services:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

In addition, section 1877 provides that an entity may not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for designated health services furnished under a prohibited referral, nor may the Secretary make payment for a designated health service furnished under a prohibited referral.

Section 1903(s) of the Social Security Act extended aspects of the referral prohibition to the Medicaid program. It denies payment under the Medicaid program to a State for certain expenditures for designated health services. Payment would be denied if the services are furnished to an individual on the basis of a physician referral that would result in the denial of payment for the services under Medicare if Medicare covered the services to the same extent and under the same terms and conditions as under the State plan.

This proposed rule incorporates these statutory provisions into the Medicare and Medicaid regulations and interprets certain aspects of the law. The proposed rule is based on the provisions of section 1903(s) and section 1877 of the Social Security Act, as amended by section 13562 of the Omnibus Budget Reconciliation Act of 1993, and by section 152 of the Social Security Act Amendments of 1994.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 10, 1998. We will also consider comments that we received in response to the final rule with comment period, "Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements," which we published in the **Federal Register** on August 14, 1995 (60 FR 41914).

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1809-P, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: hcfa1809p.hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1809-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

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FOR FURTHER INFORMATION CONTACT: Joanne Sinsheimer (410) 786-4620.

SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this proposed rule, we are providing the following table of contents:

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provision of such services does not present a risk of program or patient abuse. * * *." As discussed in the August 1995 final rule, it is our interpretation that this paragraph is intended to provide for the possibility of our liberalizing the conditions described in section 1877(b)(2)(A)(ii)(II); that is, the conditions concerning the provision of services in "another building" that is used by a group practice.

- The ancillary services must be billed by one of the following:
  + The physician performing or supervising the services.
  + A group practice of which the physician is a member under a billing number assigned to the group practice. (Prior to January 1, 1995, this provision did not require that the services be billed under a group practice's billing number.)
  + An entity that is wholly owned by the physician or group practice.

The August 1995 final rule incorporated into our regulations an in-office ancillary services exception that was based on the statutory provision, as it was in effect on January 1, 1992, at § 411.355(b). This proposed rule would revise § 411.355(b) to conform it to the current statutory provision. That is, it would—

- Specify that the exception does not apply to durable medical equipment (other than infusion pumps) or to parenteral and enteral nutrients, equipment, and supplies; and
- Revise paragraph (b)(2) of § 411.355 to require that the services be furnished in one of the following locations:
  + A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services.
  + A building that is used by the group practice for the provision of some or all of the group's clinical laboratory services.
  + A building that is used by the group practice for the centralized provision of the group's designated health services (other than clinical laboratory services).
- Indicate that when a group practice bills for ancillary services, the services must be billed under a billing number assigned to the group practice.

We have also made several other changes to the in-office ancillary services exception that we discuss in section III of this preamble.

For purposes of the in-office ancillary services exception, the August 1995 final rule also defined "direct supervision" at § 411.351. The rule defines this term as supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed. This proposed rule would retain that definition, with several changes that are meant to clarify the meaning of the term "present in the office suite." We discuss these changes in section III of this preamble.

c. Exception—certain prepaid health plans

Section 1877(b)(3) specifies that the prohibition on referrals does not apply to services furnished by certain prepaid health plans. To qualify for the exception, the services must be furnished by a Federally-qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Services Act) to its enrollees or by a prepaid health care organization to its enrollees under a contract or agreement with Medicare under one of the following statutory authorities:

- Section 1876, which authorizes us to enter into contracts with health maintenance organizations and competitive medical plans to furnish covered items and services on a risk-sharing or reasonable cost basis.
- Section 1833(a)(1)(A), which authorizes payment for Medicare Part B services to prepaid health plans on a reasonable cost basis.
- Section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972, both of which authorize us to conduct demonstration projects involving payments on a prepaid basis.

The August 1995 final rule incorporated section 1877(b)(3) into our regulations at § 411.355(c). We are proposing to set forth at § 435.1012(b) an exception for services provided by organizations analogous to those cited above to enrollees under the Medicaid program. We discuss this proposal in section III of this preamble.

d. Other exceptions

Effective January 1, 1995, section 1877(b)(4) authorizes the Secretary to provide in regulations for additional exceptions for financial relationships, beyond those specified in the statute, if she determines that they do not pose a risk of Medicare program or patient abuse. The Secretary determined, based on the rationale explained in the August 1995 final rule, that referrals for certain clinical laboratory services furnished in an ambulatory surgical center or end stage renal disease facility, or by a hospice do not pose a risk of Medicare program or patient abuse. The Secretary found no risk of abuse when payments for these services are included in the ambulatory surgical center payment rate, the end stage renal disease composite payment rate, or as part of the hospice payment rate, respectively. Therefore, the August 1995 final rule incorporated an exception for those services into our regulations at § 411.355(d). This proposed rule would retain that provision, with a change discussed below. Because this proposed rule covers 10 additional designated health services, this exception would now apply to any of the designated health services provided in the same manner.

As we noted in the August 1995 final rule, we excepted the listed services because they are furnished as part of a composite rate that cannot vary in response to utilization. We are amending § 411.355(d) to allow the Secretary to except services furnished under other payment rates that the Secretary determines provide no financial incentive for either underutilization or overutilization, or any other risk of program or patient abuse. We are specifically soliciting comments on whether there are analogous composite rates under the Medicaid program that are similarly guaranteed not to result in program or patient abuse. Commenters who are interested in this issue should demonstrate why they believe a particular kind of service should qualify for the exception.

4. Exceptions That Apply Only to Certain Ownership or Investment Interests

The statute also provides that certain ownership or investment interests do not constitute a "financial relationship" for purposes of the section 1877 prohibition on referrals.

a. Exception—certain investment securities and shares

Under section 1877(c), the prohibition on referrals does not apply in the case of ownership by a physician (or immediate family member) of the following:

- Investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be purchased on terms generally available to the public and that are—
- Securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or

to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space by a lessor that is a potential source of patient referrals to the lessee, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor. (Meeting the fair market value standard is a requirement for several of the other compensation-related exceptions in the statute. We discuss these other exceptions later in this preamble.)

The August 1995 final rule incorporated the provisions of section 1877(e)(1)(A) into our regulations at § 411.357(a), without imposing any additional requirements. This proposed rule would retain § 411.357(a). In addition, the final rule incorporated the definition of "fair market value" in § 411.351. This proposed rule would retain the definition. Also, since the statute requires that fair market value be "consistent with the general market value," we have added to the definition an explanation of "general market value."

b. Exception—rental of equipment

Section 1877(e)(1)(B) provides an exception for payments made by a lessee of equipment to the lessor for the use of the equipment if the following conditions are met:

- The lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease.
- The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the rental or lease and is used exclusively by the lessee when being used by the lessee.
- The lease provides for a term of rental or lease of at least 1 year.
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The lease would be commercially reasonable even if no referrals were made between the parties.
- The lease meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

The August 1995 final rule incorporated this provision into our regulations at § 411.357(b), without imposing any additional requirements. This proposed rule would retain § 411.357(b), with minor editorial changes.

c. Exception—bona fide employment relationship

Under section 1877(e)(2), any amount paid by an employer to a physician (or an immediate family member of the physician) who has a bona fide employment relationship with the employer for the provision of services does not constitute a compensation arrangement for purposes of the prohibition if the following conditions are met:

- The employment is for identifiable services.
- The amount of the remuneration under the employment is consistent with the fair market value of the services and (except for certain productivity bonuses) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.
- The remuneration is made in accordance with an agreement that would be commercially reasonable even if no referrals were made to the employer.
- The employment meets any other requirements the Secretary may impose by regulation as needed to protect against Medicare program or patient abuse.

The statute provides that, under this exception, a productivity bonus that is based on services performed personally by the physician (or immediate family member) does not violate the "volume or value of referrals" standard.

"Employee" is defined in section 1877(h)(2) as an individual who would be considered to be an employee of the entity under the usual common law rules that apply in determining employer-employee relationships, as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986.

The August 1995 final rule incorporated the provisions of section 1877(e)(2) into our regulations at § 411.357(c), without imposing any additional requirements. This proposed rule would retain § 411.357(c), but with additional requirements that we describe in section III. The final rule also incorporated the definition of "employee" into our regulations at § 411.351. Again, this proposed rule would retain that definition.

d. Exception—personal service arrangements

Under section 1877(e)(3)(A), remuneration from an entity under an arrangement (including remuneration for specific physician services furnished to a nonprofit blood center) does not constitute a compensation arrangement for purposes of the prohibition on referrals if the following conditions are met:

- The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement.
- The arrangement covers all of the services to be furnished by the physician (or immediate family member) to the entity.
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- The term of the arrangement is for at least 1 year.
- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as described below) is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates State or Federal law.
- The arrangement meets any other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse.

The August 1995 final rule incorporated section 1877(e)(3)(A) into our regulations at § 411.357(d)(1), without imposing any additional requirements. This proposed rule would retain § 411.357(d)(1), with several changes that we discuss in section III of this preamble.

Section 1877(e)(3)(B)(i) provides that, in the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account, directly or indirectly, the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

- No specific payment is made (directly or indirectly) under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.
- If the plan places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii), the plan

services provided by an entity that qualifies as a "hospital" under the Medicare conditions of participation. We further believe that section 1877(d)(3) covers any "designated health services" provided by a hospital, rather than just "inpatient or outpatient hospital services," because hospitals can provide services to individuals who are neither inpatients nor outpatients (for example, they provide laboratory services to outside patients).

E. Exceptions That Apply Only to Compensation Arrangements

1. A new exception for all compensation arrangements that meet certain standards

Section 1877 of the Act contains a number of exceptions to the referral prohibition that apply only to compensation arrangements. Section 1877(e) contains eight exceptions to the referral prohibition based specifically on various kinds of compensation arrangements, and these are reflected in § 411.357 of the August 1995 final rule. If a physician's (or family member's) arrangement with an entity falls within one of the categories covered by these exceptions, and the arrangement meets the specific criteria listed for that category, the physician is not prohibited from making referrals to the entity.

It has come to our attention that the statutory categories, because of their specificity, do not encompass some compensation arrangements even though they may be common in the provider community, are based on fair market value or are otherwise commercially reasonable, and do not reflect the volume or value of a physician's referrals. For example, a physician can continue to make referrals to an entity under section 1877(e)(8)(B) even if the physician purchases items from the entity, provided the items are furnished at fair market value. On the other hand, the law does not exempt from the referral prohibition situations in which entities purchase items from a physician, even if the purchase price is comparably fair.

In light of the increase in recent years of integrated delivery systems, and the complex nature of financial arrangements between physicians and entities, it is our view that any compensation arrangements that are based on fair value, and that meet certain other criteria, should be excepted. Therefore, we are proposing to establish a new paragraph (l) in § 431.357 to provide an additional exception for compensation arrangements under the authority of section 1877(b)(4). This provision allows the Secretary to establish exceptions for any other financial relationship that she determines, and specifies in regulations, does not pose a risk of program or patient abuse. To meet this requirement, we are proposing an exception for any compensation arrangement between a physician (or immediate family member), or any group of physicians (even if the group does not qualify as a group practice) and an entity, provided the arrangement meets the following criteria, which we believe by their terms will prevent program or patient abuse. The arrangement must—

- Be in writing, be signed by the parties, and cover only identifiable items or services, all of which are specified in the agreement;
- Cover all of the items and services to be provided by the physician or immediate family member to the entity or, alternatively, cross refer to any other agreements for items or services between any of these parties.
- Specify the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement covering the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change;
- Specify the compensation that will be provided under the arrangement, which has been set in advance. The compensation must be consistent with fair market value and not be determined in a manner that takes into account the volume or value of any referrals (as defined in § 411.351), payments for referrals for medical services that are not covered under Medicare or Medicaid, or other business generated between the parties;
- Involve a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; and
- Meet a safe harbor under the anti-kickback statute or otherwise be in compliance with the anti-kickback provisions in section 1128B(b) of the Act.

We would advise the parties involved in a compensation arrangement to use this exception if they have any doubts about whether they meet the requirements in the other exceptions listed in § 411.357.

2. A new exception for certain forms of "de minimis" compensation

We are aware that there are a number of situations in which physicians or their immediate family members receive compensation in the form of incidental benefits that are not part of a formal, written agreement. For example, a physician might receive free samples of certain drugs or chemicals from a laboratory, training sessions for his or her staff before entering into an agreement with a facility that furnishes a designated health service, or training sessions that are not considered part of the agreement. Also, a provider might furnish a physician with free coffee mugs or note pads. We are exercising our authority under section 1877(b)(4) to create a new exception that we believe will allow physicians or their family members to receive de minimis amounts of compensation, without a risk that the compensation will result in any Medicare program or patient abuse.

We have drafted the exception, which would appear at § 411.357(k), to apply to noncash items or services. Items cannot include cash equivalents, such as gift certificates, stocks or bonds, or airline frequent flier miles. We propose to limit the exception to a value of $50 per gift, with a $300 per year aggregate. This exception would apply only in situations in which the entity providing the compensation makes it available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services. In addition, any compensation a physician or family member receives from an entity cannot be based in any way on the volume or value of the physician's referrals. We believe the criteria for this exception, by their terms, will prevent patient or program abuse.

3. The "volume or value of referrals" standard

Most of the exceptions in the law covering specific kinds of compensation arrangements state that the compensation involved cannot reflect the volume or value of any referrals. (We have included a similar standard in the two new compensation exceptions described above.) We are applying our interpretation of that standard as it appears in section III.A.6 under our discussion of the criteria a group of physicians must meet to qualify as a "group practice." In that section, we describe what constitutes a "referral" for purposes of the "volume or value" standard.

The volume or value of referrals standard appears in the exceptions for the rental of space or equipment, bona fide employment relationships, personal services arrangements, physician recruitment, isolated transactions, and group practice arrangements with a

allowing productivity bonuses under the definition of a group practice in section 1877(h)(4)(B)(i). This provision allows group practices to pay members a productivity bonus only if the bonus is not directly related to the volume or value of a physician's own referrals. We are equalizing the provisions in this regard under the authority in section 1877(e)(2)(D), which allows the Secretary to impose by regulation other requirements as are needed to protect against patient or program abuse. Without this change, we believe that physicians have an incentive to overutilize designated health services, since they can be compensated directly for every self referral they make.

We would like to point out that because we have interpreted the concept of a "referral" to involve only a physician's requests for designated health services covered under Medicare or Medicaid, the new requirement will in no way affect a physician's ability to receive a productivity bonus for any nondesignated health services or noncovered services he or she refers or performs, or designated health services referred by another physician.

The bona fide employment exception does not, by its terms, allow for indirect compensation based on profit sharing and productivity bonuses for a physician's "incident to" services. The group practice definition does allow for such compensation. We do not believe that we can equalize the provisions in this regard, since it is our view that there are situations in which compensating a physician even indirectly for his or her self referrals could encourage overutilization and abuse.

7. Exception for personal services arrangements

Section 1877(e)(3) excepts from the referral prohibition situations involving remuneration from an entity under a personal services arrangement if certain criteria are met. The statute does not specify to whom the remuneration must be paid or for what kinds of services, although we believe the services must be "personal services."

One of the criteria for this exception requires that the arrangement cover all of the services to be furnished to the entity by the referring physician or an immediate family member of the physician. Therefore, we are interpreting this exception as covering services furnished by these individuals. We believe there is nothing in the statute to preclude a physician or family member from having personal services arrangements with several entities. (For example, a physician might have a contract to serve as a hospital's medical director and another contract with an unrelated group practice to perform surgery.) However, the statute does appear to require, in section 1877(e)(3)(A)(ii), that an excepted arrangement with one entity cover all of the services to be provided by the physician (or family member) to that entity.

We are aware that at times it will not be logical for all of a physician's or family member's contracts for personal services to be in one agreement. However, we are also aware that entities have used multiple contracts, at times, in devising schemes to reward physicians for their referrals. In order to provide physicians and entities with more flexibility than the statutory requirement that all services appear in one agreement, we propose to allow multiple agreements, provided that the agreements each meet all of the requirements described in section 1877(e)(3) and all separate agreements between the entity and the physician and the entity and any family members incorporate each other by reference. We base our proposal on section 1877(b)(4), which allows the Secretary to specify, in regulations, an exception for any other financial relationship that she determines does not pose a risk of patient or program abuse. In this case, because all excepted agreements will be subject to the fair market value and other standards, and because each agreement will make us aware of all other agreements, we see no potential risk for abuse.

It is our view that "personal services" are not simply the generic Medicare services (which are defined in § 400.202 to include "items") but are services of any kind performed personally by an individual for an entity (but *not* including any items or equipment). We are using the broader, more common notion of what constitutes a "service" based on the fact that all kinds of business relationships can trigger the referral prohibition; hence, the exception should be read to apply to business-oriented services in general.

We are also interpreting the exception to mean that the physician or family member can actually perform the services, or that these individuals can enter into an agreement to provide the services through technicians or others whom they employ. A physician or family member cannot, though, include equipment or other items as part of an excepted personal services arrangement. For example, if a hospital contracts with a nephrologist to provide dialysis services to its patients, the physician could have a personal services arrangement with the hospital even if the dialysis services are actually furnished by technicians whom the physician employs. However, if the physician also provides dialysis equipment to the hospital, this arrangement would have to separately meet the exception for the rental of equipment in section 1877(e)(1), since we do not regard items or equipment as "personal services."

The personal services exception specifies that compensation under an arrangement cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. However, this requirement is qualified to allow compensation to reflect these under certain situations in which there is a physician incentive plan between a physician and an entity. We would like to emphasize that the physician incentive plan aspect of section 1877(e)(3) applies only in the context of personal services arrangements, and not to any other compensation arrangements.

"Physician incentive plans" are defined in section 1877(e)(3)(B)(ii) as certain compensation arrangements between an entity and a physician or physician group. We have defined a physician group for purposes of the physician incentive rules more broadly than a group practice under section 1877, so that a group practice is a subset of physician groups. (A final rule with comment period governing physician incentive plans was published on March 27, 1996, at 61 FR 13430. This rule was amended on December 31, 1996, at 61 FR 69034.)

A physician incentive plan is any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity. We believe that the incentive plan qualification applies only when the entity paying the physician or physician group is the kind of entity that enrolls its patients, such as a health maintenance organization. Section 1877(b)(3), the exception for prepaid plans, does exempt from the referral prohibition almost all designated health services provided by these entities to Medicare patients who are enrollees. In addition, this regulation proposes to exempt services provided to Medicaid patients by analogous kinds of entities (see our discussion of this issue earlier in this preamble). Nonetheless, the personal services exception, with its physician incentive aspect, is still a viable exception. This exception could

must furnish information to the Secretary (that is, to HCFA). However, we are taking the position that the provision allows us to require that entities report directly to the States. Section 1903(s) provides that section 1877(f) applies "in the same manner" in the Medicaid program as it does in Medicare. In Medicare, the reports are made to the Secretary, the official who is responsible for making payment under Medicare. "In the same manner," in the context of the Medicaid program, would mean that the reports would be made to the entity that makes payment; that is, the State, thus maintaining a symmetry between reporting in the two programs.

We have taken this position because, under section 1903(s), it is the States that are at risk of losing FFP for paying improper claims for designated health services submitted by entities that have financial relationships with physicians. Therefore, in order to ensure that FFP will be available, States must determine whether a physician has a financial relationship with an entity that would prohibit referrals under Medicare. Our interpretation will allow States to protect themselves and to avoid any duplication of effort with HCFA.

We are amending the regulations to create a new Subpart C, "Disclosure of Information by Providers for Purposes of the Prohibition on Certain Physician Referrals." In § 455.108, "Basis," we state that, based on section 1903(s), we are applying the reporting requirements of section 1877(f) and (g) to Medicaid providers of designated health services. Section 455.109(a) would state that the Medicaid agency must require that each entity that furnishes designated health services submit information to the Medicaid agency concerning its financial relationships, in such form, manner, and at such times as the agency specifies. Although the statute requires that entities submit information to the Secretary, we believe that the State should receive this information in the Medicaid context, in order to help States ensure that they will receive FFP.

Section 455.109(b) would specify that the requirements of § 455.109(a) do not apply to entities that provide 20 or fewer designated health services under the State plan during a calendar year, or to any entity for items or services provided outside the United States. We have derived the limit of 20 or fewer designated health services from the Medicare regulation interpreting section 1877(f) (§ 411.361).

Section 455.109(c) would specify that the information submitted to the Medicaid agency under § 455.109(a) must include at least the following:

- The name and Medicaid State Specific Identifier (MSSI) of each physician who has a financial relationship with the entity that provides services.
- The name and MSSI of each physician who has an immediate relative (as defined in § 411.351) who has a financial relationship with the entity.
- The covered items and services furnished by the entity.
- With respect to each physician identified above, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement), if requested by the Medicaid agency.

Section 455.109(d) would define a reportable financial relationship as an ownership or investment interest or any compensation arrangement, as defined in § 411.351, including relationships that qualify for an exception described in §§ 411.355 through 411.357.

Section 455.109(e) would specify that—

- Entities that are subject to the reporting requirements must submit the required information on a prescribed form within the time period specified by the Medicaid agency. Similarly, entities must report to the Medicaid agency all changes in the submitted information within a timeframe specified by the State. We believe that States have the discretion to determine these deadlines in line with § 455.109(a), which requires that the Medicaid agency gather information on financial relationships in such form, manner, and at such times as the agency specifies.
- Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to the Medicaid State agency, HCFA, or the OIG.

Section 455.109(f) would reflect section 1877(g)(5), specifying that any entity that is required, but has failed, to meet the reporting requirements of § 455.109(a), is subject to a civil money penalty of not more than $10,000 for each day of the period beginning on the day following the applicable deadline until the information is submitted. It would further specify that assessment of the penalty will comply with the applicable provisions of 42 CFR part 1003.

IV. Our Responses to Questions About the Law

In this section of the preamble, we have included some of the most common questions concerning physician referrals that we have received from physicians, providers, and others in the health care community. (Note that, in this section, we are using the term "provider" in the generic sense to include all providers of health care services. That is, we are not using the term with the special meaning given in our regulations at § 400.202.) We summarize these questions below and present our interpretation of how we believe the law applies in the situations that have been described to us. We have organized this section so that the issues raised by the questions appear in the order in which they appear in the regulation.

A. Definitions

1. Compensation Arrangement

What is an "indirect" compensation arrangement? We defined a "compensation arrangement" in the August 1995 final rule, in line with the statute, as any arrangement involving any remuneration, *direct or indirect*, between a physician (or family member) and an entity. This means that a compensation arrangement can result when remuneration flows from an entity to a physician or family member, or from a physician or family member to an entity. We have received a number of inquiries on what constitutes an "indirect" compensation arrangement. We believe that a physician or family member can receive compensation from an entity, even if the payment is "funneled through" a business or other entity or association and even if the payment changes form before the physician actually receives it.

For example, suppose that a hospital has contracted with a group practice for the group to furnish physician services and to otherwise staff the hospital. The hospital pays the group practice, which might be a professional corporation or a similar association or entity, for the physician services under a personal services arrangement, rather than directly compensating the individual physicians. The group practice, in turn, pays the individual physicians a salary that in some way reflects the hospital's payments.

It is our position that, in such a scenario, each physician has been indirectly compensated by the hospital for his or her own services. As a result, the physicians have a compensation arrangement with the hospital. In the absence of an exception, the physicians would be prohibited from referring to the hospital for the furnishing of designated health services.

We believe that a physician has received indirect compensation whether the "intervening" professional

association, corporation, or other entity directly receiving payment is a group practice or any other type of physician or nonphysician owned entity. We also believe a physician can receive indirect compensation through a nonprofit enterprise if that enterprise is controlled by an individual who is in a position to influence the physician's referrals. For example, the owner of a clinical laboratory who also serves as the director of a nonprofit research facility could provide a physician with research grants in exchange for referrals to the laboratory. We are considering regarding as indirect compensation any payment to a physician that passes from an entity that provides for the furnishing of designated health services, no matter how many intervening "levels" the payment passes through or how often it changes form. We directly solicit comments on this approach.

We would also like to reiterate a point that we made in the preamble to the August 1995 final rule. Just because a hospital or similar entity is affiliated with a physician or group of physicians does not automatically mean that the hospital or similar entity is compensating the physicians. Physicians and entities can have joint ventures and similar relationships in which the hospital or similar entity and the physicians share profits, but do not compensate each other.

Which exceptions apply in indirect situations? We have also received questions about which exception applies when an indirect payment changes form. For example, in the situation described above, a hospital makes payments to a group practice under a personal services arrangement. The group practice, in turn, passes the payments on in the form of salary payments to its physician employees. We believe that the compensation at issue involves a personal services arrangement between the hospital and the group practice (see the discussion in III.E.6 of this preamble about personal services arrangements between entities and group practices, rather than between entities and individual physicians).

We are interpreting the statute to focus on the payment the entity furnishing designated health services initially makes to determine the appropriate exception. In this case, the hospital is making a payment under a personal services arrangement, and is not in any way making a salary payment to its own employees. Thus, we believe the physicians could make referrals to the hospital if the group practice's personal services arrangement with the hospital meets the criteria under the personal services exception.

It is our view that the salary payment from the group practice to its physician employees is a payment separate from the remuneration flowing indirectly from the hospital to the physicians. As a result, this payment, as a payment from the group practice, should itself have no additional effect on a physician's ability to refer to the hospital. (The nature of the payment might, however, affect whether the physicians qualify as a group practice. See the discussion in section III.A.6 of this preamble covering the characteristics of a group practice.)

2. Entity

What are the characteristics of an "entity" that provides for the furnishing of designated health services? We have received a number of questions about what constitutes an "entity" involved in the furnishing of designated health services and who owns that entity. For example, a group of individuals asked us whether they own a hospital based solely on the fact that they own the building that houses the hospital. We believe that an "entity" for purposes of section 1877 is the business, organization, or other association that actually furnishes, or provides for the furnishing of, a service to a Medicare or Medicaid patient and bills for that service (or receives payment for the service from the billing entity as part of an "under arrangements" or similar agreement).

An "entity," therefore, does not include any person, business, or other organization or association that owns the components of the operation—such as owning the building that houses the entity or the equipment the entity uses—without owning the operation itself. For example, a physician might own and operate an MRI machine in his or her office. If this physician enters into a lease arrangement for the use of the MRI machine every Tuesday by the physician down the hall, who bills for the services, we believe that the physician down the hall is the entity providing MRI services to his or her patients on Tuesday. This physician could refer patients for MRI services if he or she qualifies for an exception, such as the in-office ancillary services exception.

When is an entity furnishing, or providing for the furnishing of, designated health services? Section 1877(a)(1)(A) prohibits a physician from making a referral to an entity "for the furnishing of designated health services" if the physician or a family member has a financial relationship with that entity. The health care community has expressed some confusion about when an entity is one involved in the "furnishing of" designated health services.

We have, for example, received questions about which entities are the relevant ones when some entities only bill for services, while others actually directly "furnish" the services. For example in an "under arrangements" situation, a hospital, rural primary care hospital, skilled nursing facility (SNF), home health agency, or hospice program contracts with a separate provider to furnish services to the hospital's, SNF's, or other contracting entity's patients, for which the hospital, SNF or other contracting entity ultimately bills.

The statutory provisions that mention "under arrangements" draw a distinction between services that are actually furnished by the hospital or SNF and those that are actually furnished by the separate, outside entity. (Under section 1861(w)(1), HCFA's payment to the hospital, SNF, or other contracting entity discharges the beneficiary's liability. "Under arrangements" situations are further referenced in sections 1861(b)(3) and 1862(a)(14).) We are aware that there are comparable agreements in the community between entities other than hospitals, SNFs, and the other contracting entities listed above, such as agreements between group practices that furnish services to HMO patients, with the HMO billing for the services.

We believe that, absent an exception, the referral prohibition applies to a physician's referrals to any entity that directly furnishes designated health services to Medicare or Medicaid patients. We believe the prohibition also applies to referrals to any entities that arrange "for the furnishing of" these services to Medicare or Medicaid patients by contracting with other providers, whenever it is the arranging entity that bills for the services.

This interpretation is consistent with the intent of the statute. Congress intended, in enacting section 1877, to prohibit referrals in situations in which a physician has a financial incentive to overutilize the various designated health services and to steer patients toward certain providers of these services. For example, a physician might routinely refer patients to a SNF in which he has a financial interest and prescribe occupational therapy (OT) services. The SNF, in turn, might contract with a separate, unrelated entity to furnish SNF patients with the OT, for which the SNF bills. Even if the physician has no relationship with the separate OT provider, he does have a

financial relationship with the SNF that is providing for "the furnishing of" OT to referred patients. As a result, the physician can potentially profit from each referral he or she makes for OT, even if the SNF must first purchase those services from an outside source before passing on the cost to its patients.

If, however, the unrelated OT entity itself bills for the services under Part B, so that the SNF only helps to make these services available to its patients, our conclusion would be different. In this situation, we do not believe that the physician has a financial incentive to overutilize OT services. As a result, we would not regard the SNF as an entity involved in "the furnishing of" a designated health service.

We also believe that a physician can have an incentive to overutilize services if he or she has a financial relationship with the entity that directly furnishes designated health services, even if this is not the entity ultimately billing for the services. In these situations, the physician can potentially recognize a profit from each referral based on the fact that the designated health services will, in essence, be sold to the entity that bills.

For example, a physician who is a member of a group practice might work in a hospital as a staff physician and refer patients to the group's own outside laboratory in which the physician has an ownership interest. The laboratory, in turn, furnishes services to hospital patients under arrangements. The hospital will therefore be billing Medicare for laboratory services furnished by the physician's own laboratory. In this case, the physician is in a position to influence how many services the laboratory will be able to "sell" to the hospital. Thus, the physician should be prohibited from making these referrals, unless one of the exceptions applies.

We believe our policy of including entities that contract for services as those that provide for "the furnishing of" designated health services is consistent with the structure of section 1877 and the way the exceptions are drafted. For example, under section 1877(b)(3), services are excepted if furnished by an organization that functions under a prepaid plan, such as an HMO. It is our understanding that such services are very often made available in a manner that is comparable to "under arrangements" situations; that is, the prepaid organization contracts with a broad range of independent suppliers and providers to furnish services to its enrollees. This exception makes no distinction between services that are furnished directly by the HMO and those that are furnished under contract by outside providers; all such services appear to be considered as furnished by the HMO, and would be excepted.

Similarly, section 1877(d)(3) excepts certain "designated health services provided by a hospital," but makes no distinctions between services the hospital itself furnishes and those furnished by the hospital under arrangements.

3. Financial Relationship

How do equity and debt qualify as ownership? The statute states that an ownership interest can be through equity or debt. We have received a number of inquiries about what this provision means and what kinds of debt situations constitute a form of ownership. We believe that "ownership through equity" refers to a direct ownership interest that does not involve debt; for example, one in which the physician or family member has actually purchased assets of a business entity with cash or other property. This interest could be in the form of stock in a publicly-held entity or an investment (such as a capital contribution) in a partnership.

We believe that a physician or family member holds an ownership interest in an entity "through debt" anytime the physician or family member has lent money or given other valuable consideration to the entity and the debt is secured (in whole or in part) by the entity or by the entity's assets or property. For example, the physician could hold such an interest by providing the entity with a note, a mortgage or by purchasing bonds. This interpretation is consistent with the definition of an ownership or control interest in section 1124(a)(3) of the Act, which governs which suppliers and providers must disclose these interests to us for purposes other than the referral prohibition. Section 1124(a)(3)(A)(ii) defines a person with an ownership or control interest as a person who is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the entity's property or assets, if the interest is worth a certain amount.

We also believe that ownership through debt can exist in any other debtor-creditor relationships that have some indicia of ownership. For example, such indicia could include the creditor's participation in revenue or profits, subordinated payment terms, low or no interest terms, or ownership of convertible debentures (bonds that a physician or family member can convert into the common stock of the issuer or an affiliate until the convertible feature expires).

However, if a physician or family member has made an unsecured or nonconvertible loan to an entity, or a loan with no other indicia of ownership, we do not believe the loan is an ownership interest. The loan would likely qualify as a compensation arrangement, to which an exception might apply.

We do not believe that a physician or family member has "ownership through debt" when either of them has received a loan *from* an entity. In ordinary business transactions, when a debtor receives a loan, this transaction in no way establishes for the debtor an ownership interest in the creditor. We also assume that in providing the loan, the creditor entity has provided remuneration to the physician or family member, resulting in a compensation arrangement. This kind of compensation arrangement could meet one of the exceptions to the prohibition. For example, the loan might be one form of payment an entity makes to a physician to recruit the physician or as part of the physician's employment contract. The loan would be an excepted arrangement if it met the fair market value and other standards in these exceptions.

Is membership in a nonprofit corporation an ownership or investment interest? We have received a number of inquiries concerning whether membership in a nonprofit corporation constitutes an ownership or investment interest in that corporation. (We are assuming that a "member" is someone who establishes, sponsors, directs, or controls a nonprofit corporation.) Most nonprofit health care corporations that are exempt from Federal income taxation are exempt under section 501(c)(3) or (4) of the Internal Revenue Code. These provisions state that the net earnings of such a corporation cannot inure to the benefit of any private shareholder or individual. Therefore, while members of such a nonprofit corporation may exercise control over the activities of the corporation, they do not have the pecuniary incentive that for-profit investors have to enhance their investment interests. As such, we do not regard being a member of these kinds of nonprofit corporations as an ownership or investment interest analogous to being a shareholder in a for-profit corporation. However, any remuneration that the physician or family member receives from the corporation, such as a salary, would be compensation and must meet an exception.

physician, which includes the provision of a designated health service.

We believe a referral would be acceptable where the referral is not for a designated health service. For example, a physician who is a general practitioner might believe that a patient has a neurological problem, but be unsure of a diagnosis. This physician could refer the patient to his or her neurologist spouse, if the referral is not a "consultation" (see our discussion of "consultations" in section III.A.7 of this preamble). That is because the referring physician has not requested a designated health service or established a plan of care including one, nor has he or she requested a consultation. We believe the referral, in this case, is for physician services, which are generally not designated health services. If the spouse, in turn, determines that the patient requires an MRI, the spouse would be the one making the referral for this designated health service.

If one member of a group practice cannot make a referral to an entity, are all other group practice physicians also precluded? Group practices have informed us that they are concerned about the definition of a "referring physician" in § 411.351, and how it affects a group when one member is precluded from referring to a particular entity that furnishes designated health services. In particular, several groups wondered whether having a physician member whose immediate relative has an unexcepted ownership interest in an entity would preclude all group practice members from referring to that entity. Groups believe that the preamble to the final rule covering referrals to clinical laboratories implied that the referral prohibition would be imputed to all physician members.

Section 411.351 defines a "referring physician" as a physician (or group practice) who makes a referral (as defined elsewhere in the regulations). We interpreted this definition to mean that when an individual group member refers, the entire group has referred. As a result, any member of a group who has an unexcepted financial relationship (or whose relative has such a relationship) with an entity could "taint" the referrals of the entire group.

We have reconsidered this issue and now propose to amend the definition to exclude any reference to the entire group practice. We believe that the statute was drafted to cover the referral behavior of individual physicians and to regulate the entities to which they refer. There does not appear to us to be any clear reason to extend the effects of one physician's relationships and behaviors to other physicians, just because they are all members of the same group practice. As several practices have pointed out to us, being members of the same group practice does not mean that physicians automatically have the opportunity, power, or incentive to exert pressure on each other to refer to their related entities.

However, in any instance in which a group member is in a position to exert influence or control over the referrals of other group physicians, the prohibition could still apply. For example, group members could be subject to sanctions if their referral patterns reveal a circumvention scheme between them. Similarly, if a group practice owner conditions payment to his or her employee members on referrals to the owner's laboratory, the employment could be a compensation arrangement that triggers the prohibition.

6. Remuneration

Do payments qualify as remuneration only if they result in a net benefit? Certain members of the provider community have requested that we interpret a payment as remuneration only if it is made in exchange for identifiable property or services. Under this theory, if the physician or entity making the payment has no expectation of or entitlement to something of value in return for the payment, there would be no compensation arrangement, even if other physicians or entities might benefit from the exchange.

In the August 1995 final regulation, we defined remuneration as "any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind," except for a narrow list of remuneration excluded from the definition by section 1877(h)(1)(C). We believe that remuneration generally involves any payment of cash, property, or services, whether or not either or both parties receive a net benefit. For example, we would regard as remuneration the repayment of a loan, even if there are no accompanying interest payments.

We base this interpretation on the statute, which excepts from compensation arrangements under section 1877(h)(1)(C) only very limited and specific types of remuneration. Among the list is the forgiveness of amounts for the correction of minor billing errors; that is, small amounts that are excused by one party in order to even out the parties' accounts. However, the statute does not except amounts that are forgiven to even out larger billing errors, nor does it contain a general exception for remuneration that does not result in a net benefit for one or both of the parties. (The correction of a large billing error might, however, qualify as an "isolated transaction" or qualify for the new exception in § 411.357(l) as part of a fair market value exchange.)

We believe that the statute is designed to prohibit referrals whenever a physician makes a payment to an entity or an entity makes a payment to a physician, regardless of who profits or gains. The statute, in our view, contains a presumption that if there has been a payment of any kind, a physician should not refer. As a result, the agency need not "look behind" each transaction to ascertain whether the physician has gained some benefit as a result of the transaction, has realized little or no net benefit, or has benefitted too much. The law does, however, designate certain very specific compensation arrangements that require that the Secretary "look behind" them and except them if the exchanges of payment meet fair market value and certain other standards.

It is our view that the one-way payments described by the providers are remuneration. If a payment does not reflect an actual fair market value exchange, it could easily serve as the vehicle for referral payments. We believe the law was meant to prevent a physician from referring to an entity if that physician (or a family member) is receiving payments of any kind that cannot be accounted for as part of a fair exchange.

B. General Prohibition—What Constitutes a Prohibited Referral

Does the prohibition apply only if a physician refers directly to a particular related entity? As we mentioned in the section above covering the definition of "entity," section 1877(a)(1) prohibits a physician from making a *referral to an entity* for the furnishing of designated health services if the physician or immediate family member of the physician *has a financial relationship* with that entity. Section 1877(h)(5) defines a referral very broadly: A referral is the request by a physician for a Part B item or service (including certain consultations). In addition, "the request or establishment of a plan of care by a physician that includes the provision of [a] designated health service" constitutes a "referral" by a "referring physician." We have interpreted this provision in § 411.351 of the August 1995 final clinical laboratory rule to mean that a physician has made a referral if he or she has made a request for a Part B item or service or a request for other items or services that includes the provision of laboratory services or if he or she has